

Studie 015
(CTN015-FCE20124)

Studienbericht

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Document 9550082

Reboxetine

CLINICAL STUDY
015

18 December 1995

Multicentre, Multinational Double-Blind Study of the Activity and Tolerability of Reboxetine vs Imipramine and Placebo in Patients Suffering from Major Depressive Episodes

(Phase III)

Final report of study
CTN015-FCE20124

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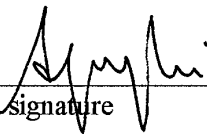
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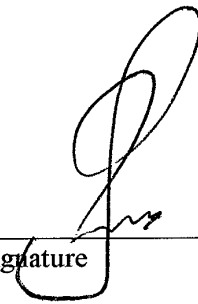
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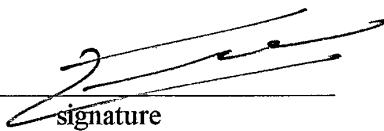


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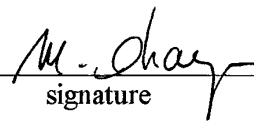
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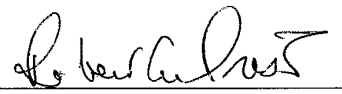
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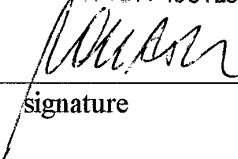

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TABLE OF CONTENTS

	Page
COVER PAGE	1
STUDY CO-ORDINATION, MANAGEMENT AND REPORTING	2
TABLE OF CONTENTS	9
LIST OF ABBREVIATIONS AND TERMS	21
SYNOPSIS	22
1. INTRODUCTION	28
2. STUDY OBJECTIVES	29
3. INVESTIGATIONAL PLAN	29
3.1 Study Design and Plan - Description and Rationale	29
3.1.1 OVERVIEW AND JUSTIFICATION	29
3.1.2 PROTOCOL AMENDMENTS	30
3.2 Ethics	31
3.2.1 ETHICS COMMITTEE	31
3.2.2 PATIENT INFORMATION	31
3.3 Study Population	32
3.3.1 INCLUSION CRITERIA	32
3.3.2 EXCLUSION CRITERIA	32
3.3.3 WITHDRAWAL CRITERIA	33
3.3.4 SAMPLE SIZE - NUMBER OF PATIENTS PLANNED	34
3.4 Treatments	34
3.4.1 TREATMENTS TO BE COMPARED	34
3.4.2 IDENTITY OF TEST TREATMENTS	35
3.4.3 DOSE SELECTION AND TIMING	35
3.4.4 METHOD OF ASSIGNING PATIENTS TO TREATMENT GROUPS	35
3.4.5 TREATMENT SUPPLY AND BLINDING	36
3.5 Treatment Procedures	36
3.5.1 CONCOMITANT THERAPY	36
3.5.2 TREATMENT ACCOUNTABILITY AND COMPLIANCE	37
3.6 Efficacy and Safety Variables	37
3.6.1 EFFICACY	37
3.6.1.1 Hamilton Depression Rating Scale	37
3.6.1.2 Clinical Global Impression	39
3.6.1.3 Montgomery and Asberg Depression Rating Scale	40
3.6.1.4 Patient Global Impression Scale	41
3.6.1.5 Relational Depression Rating Scale	41
3.6.1.6 Cognitive Function Evaluation	41
3.6.2 SAFETY	41
3.6.2.1 Adverse Events	41

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

TABLE OF CONTENTS (continued)

	Page
3.6.2.2 Clinical and Laboratory Tests	43
3.7 Study Procedures and Flow Chart	44
3.7.1 SCHEDULE OF ASSESSMENTS	44
3.7.2 PROCEDURES AT EACH VISIT	45
3.8 GCP Compliance, Data Quality Assurance	45
3.9 Statistical Analysis	46
3.9.1 DETERMINATION OF SAMPLE SIZE	46
3.9.2 ANALYSES CARRIED OUT	46
3.9.2.1 Baseline Comparability of Treatments Groups	46
3.9.2.2 Efficacy Analyses	47
3.9.2.3 Safety Analyses	49
3.9.2.4 Changes in the Conduct of the Study or Planned Analysis	50
3.10 Data Management	51
4. STUDY PATIENTS	52
4.1 Disposition of Patients	52
4.2 Protocol Deviations	53
4.3 Demographic Data	54
4.3.1 DIAGNOSIS AND HISTORY OF THE DEPRESSIVE DISORDER	55
4.3.2 SEVERITY OF DEPRESSION	56
4.3.3 PREVIOUS ANTIDEPRESSANT TREATMENTS	57
4.3.4 MEDICAL HISTORY	57
5. STUDY MEDICATION AND COMPLIANCE	58
6. CONCOMITANT MEDICATIONS	59
7. EFFICACY RESULTS	59
7.1 Hamilton Depression Rating Scale	59
7.2 Clinical Global Impression	61
7.2.1 SEVERITY OF ILLNESS	61
7.2.2 GLOBAL IMPROVEMENT	62
7.2.3 EFFICACY INDEX	62
7.3 Montgomery and Asberg Depression Rating Scale	62
7.4 Relational Depression Rating Scale	63
7.5 Efficacy conclusions	63
8. SAFETY RESULTS	65
8.1 Safety Population and Extent of Exposure	65
8.1.1 NUMBER OF PATIENTS IN SAFETY ANALYSIS	65
8.1.2 TOTAL DRUG EXPOSURE	65
8.2 Adverse Events	65
8.2.1 ANALYSIS OF ADVERSE EVENTS	65
8.2.1.1 Absolute and Per Cent Frequency	66

Pharmacia

Document 9550082

TABLE OF CONTENTS (continued)

	Page
8.2.1.2 Occurrence	67
8.2.1.3 Overall Risk	67
8.2.1.4 Dose-relationship	67
8.2.1.5 Maximal Severity	68
8.2.1.6 Duration	68
8.2.1.7 Symptomatic Treatment	68
8.2.1.8 Modification of Study Medication and Patient Outcome	69
8.2.1.9 Prevalence	69
8.2.1.10 Relationship Between Adverse Events and Study Medication	70
8.2.2 ADVERSE EVENT SUMMARY	70
8.2.2.1 Severity of Adverse Events	70
8.2.2.2 Age- and Gender-Related Effects	71
8.2.2.3 Frequently Reported Adverse Events	72
8.2.3 SERIOUS ADVERSE EVENTS, DEATHS AND ADVERSE EVENTS ASSOCIATED WITH WITHDRAWAL	74
8.2.3.1 Serious Adverse Events and Deaths	74
8.2.3.2 Adverse Events Associated with Withdrawal	74
8.3 Laboratory Tests	77
8.3.1 SUMMARY STATISTICS OF LABORATORY VALUES	77
8.3.2 URINALYSIS	78
8.3.3 ABNORMAL LABORATORY VALUES	78
8.3.4 ABNORMAL LABORATORY VALUES OF CLINICAL RELEVANCE	78
8.4 Vital Signs	79
8.4.1 BLOOD PRESSURE AND HEART RATE	79
8.4.2 BODY WEIGHT	80
8.4.3 BODY TEMPERATURE	80
8.5 Electrocardiogram	80
8.6 Safety Conclusions	81
9. DISCUSSION	84
10. CONCLUSION	89
11. REFERENCES	90

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Pharmacia

Document 9550082

		Page
Tables		93
Table 1	Number of patients by centre, visit and treatment	94
Table 2	Patient disposition	99
Table 3	End of study: reasons for discontinuation and visit at which discontinuation occurred, by assigned treatment	100
Table 4	Protocol violations at admission	101
Table 5	Randomisation: assigned treatment vs randomised treatment	102
Table 6	Compliance to schedule time as per protocol	103
Table 7	Concomitant drugs not allowed by protocol grouped by active principle. Number of patients	106
Table 8	Concomitant drugs not allowed by protocol grouped by class. Number of patients	107
Table 9	Demography by assigned treatment - age, weight, height	108
Table 10	Demography by assigned treatment - race	109
Table 11	Diagnosis and history of mental disorders by sex and assigned treatment	110
Table 12	Diagnosis and history of mental disorders by sex and assigned treatment	112
Table 12.1	Mini Mental State - Total score	115
Table 13	Previous antidepressive treatment by active principle	116
Table 14	Medical history and admission examination findings of screened patients by sex and assigned treatment	118
Table 15	Medical history and admission examination findings of screened patients by body system, sex and assigned treatment	124
Table 16	Experimental treatment: number of patients according to dose taken on each day and on days of assessment during therapy by assigned treatment	125
Table 16.1	Experimental treatment: number of patients who switched from low to high dose by assigned treatment	128
Table 17	Experimental treatment: distribution of patients according to capsules taken by assigned treatment	129
Table 18	Concomitant drugs by active principle: number of patients taking at least one concomitant medication by assigned treatment and initial period of administration	130

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Pharmacia

Document 9550082

Table 19	Hamilton Depression Rating Scale: summary statistics on total score according to time interval by assigned treatment	136
Table 20	Factorialisation Hamilton Depression Rating Scale: summary statistics on score of each factor according to time interval by assigned treatment	137
Table 21	Hamilton Depression Rating Scale: summary statistics on score of each item according to time interval by assigned treatment	141
Table 22	Hamilton Depression Rating Scale: summary statistics on total score at last assessment by assigned treatment	162
Table 23	Factorialisation Hamilton Depression Rating Scale: summary statistics on score of each factor at last assessment by assigned treatment	163
Table 24	Hamilton Depression Rating Scale: summary statistics on score of each item at last assessment by assigned treatment	167
Table 25	Efficacy: classification of patients according to protocol criteria on total score of Hamilton Depression Rating Scale over time by assigned treatment	188
Table 26	Efficacy: classification of patients according to protocol criteria on total score of Hamilton Depression Rating Scale at last assessment vs Day 0 by assigned treatment	189
Table 27	Clinical Global Impression: Severity of Illness according to time interval by assigned treatment	190
Table 28	Clinical Global Impression: Severity of Illness at last assessment by assigned treatment	192
Table 29	Clinical Global Impression: Severity of Illness shift table (last value vs Day 0) by assigned treatment	193
Table 30	Clinical Global Impression: global improvement according to time interval by assigned treatment	194
Table 31	Clinical Global Impression: global improvement at last assessment by assigned treatment	195
Table 32	Clinical Global Impression - Efficacy Index according to time interval by assigned treatment	196
Table 33	Clinical Global Impression - Efficacy Index at last assessment by assigned treatment	197
Table 34	Montgomery and Asberg Depression Rating Scale: summary statistics on total score according to time interval by assigned treatment	198

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Pharmacia

Document 9550082

Table 35	Montgomery and Asberg Depression Rating Scale: summary statistics on score of each item according to time interval by assigned treatment	199
Table 36	Montgomery and Asberg Depression Rating Scale: summary statistics on total score at last assessment by assigned treatment	209
Table 37	Montgomery and Asberg Depression Rating Scale: summary statistics on score of each item at last assessment by assigned treatment	210
Table 38	Relational Depression Rating Scale: summary statistics on total score according to time interval by assigned treatment	220
Table 39	Relational Depression Rating Scale: summary statistics on score of each item according to time interval by assigned treatment	221
Table 40	Relational Depression Rating Scale: summary statistics on total score at last assessment by assigned treatment	233
Table 41	Relational Depression Rating Scale: summary statistics on score of each item at last assessment by assigned treatment	234
Table 42	Adverse events: frequency (95% C.I.) of patients who complained of at least one adverse event during therapy by sex and assigned treatment	246
Table 43	Adverse events: frequency (95% C.I.) of patients who complained of at least one adverse event during therapy by age and assigned treatment	247
Table 44	Adverse events: frequency (95% C.I.) of patients who complained of at least one adverse event during therapy by DSM-III classification and assigned treatment	248
Table 45	Adverse events: number of adverse events and patients who complained of them during therapy by assigned treatment and sex	249
Table 46	Adverse events: number of adverse events and patients who complained of them during therapy by assigned treatment, body system and sex	258
Table 47	Adverse events: number of adverse events and patients who complained of them during therapy by assigned treatment and sex, grouped by body system	277
Table 48	Adverse events: occurrence of adverse events according to time of onset by assigned treatment	280
Table 49	Adverse events: occurrence of adverse events according to time of onset by assigned treatment and body system	288

Pharmacia

Document 9550082

Table 50	Adverse events: occurrence of adverse events according to time of onset by assigned treatment and grouped by body system	306
Table 51	Adverse events: number of adverse events according to dose taken the day of onset and three days before by severity and assigned treatment	309
Table 52	Adverse events: number of patients who complained of at least one adverse event by maximal severity level, sex, age, DSM-III	326
Table 53	Number of patients who complained of adverse events by maximal severity level, sex and assigned treatment	327
Table 54	Number of patients who complained of adverse events, grouped by body system, by maximal severity level, sex and assigned treatment	342
Table 55	Adverse events: duration of episodes by assigned treatment	346
Table 56	Adverse events: number of adverse events by symptomatic treatment and assigned treatment	354
Table 57	Adverse events by action on study drug and assigned treatment	360
Table 58	Adverse events: disappeared after action on study drug and reappeared on resuming treatment by assigned treatment	368
Table 59	Adverse events: outcome of events at the end of the therapy by action on study drug and assigned treatment	371
Table 60	Adverse events: prevalence of adverse events according to time interval by assigned treatment	387
Table 61	Adverse events: prevalence of adverse events according to time interval by assigned treatment and body system	397
Table 62	Adverse events: prevalence of adverse events according to time interval by assigned treatment and grouped by body system	417
Table 63	Adverse events by relationship to the experimental treatment and assigned treatment	420
Table 64	Adverse events present at last day of treatment and their relationship to study medication (only patients who withdrew from the study for adverse events)	427
Table 65	Laboratory test: haematology and blood chemistry statistical analysis according to time interval by assigned treatment	433
Table 66	Urinalysis: number and percentage of patients according to time interval, by assigned treatment and sex	450
Table 67	Urinalysis: number and percentage of patients at baseline and last assessment, by assigned treatment and sex	453

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Pharmacia

Document 9550082

Table 68	Urinalysis: shift table - number of patients with absent or present urinalysis value at each evaluation time as compared to pre-treatment evaluation, by assigned treatment	456
Table 69	Urinalysis: shift table - number of patients with absent or present urinalysis value at last assessment as compared to pre-treatment evaluation, by assigned treatment	459
Table 70	Urinalysis: shift table - number of patients with abnormal or normal urinalysis value at each evaluation time as compared to pre-treatment evaluation, by assigned treatment (specific gravity)	462
Table 71	Urinalysis: shift table - number of patients with abnormal or normal urinalysis value at last assessment as compared to pre-treatment evaluation, by assigned treatment (specific gravity)	465
Table 72	Laboratory test: haematology and blood chemistry - shift table. Number of patients with values below, within or above the normal range according to time interval as compared to pre-treatment, by assigned treatment	468
Table 73	Laboratory test: number and percentage of patients with laboratory abnormalities of clinical relevance	476
Table 74	Blood pressure and heart rate: summary statistics according to time interval by assigned treatment	484
Table 75	Blood pressure and heart rate: summary statistics on changes from baseline observed during treatment according to time interval by assigned treatment	487
Table 76	Blood pressure and heart rate: number and percentage of patients with decrease or increase vs baseline of clinical relevance according to time interval by assigned treatment	490
Table 77	Blood pressure and heart rate: absolute number of patients showing clinically relevant changes, compared to baseline, once, twice or more times during the therapy	493
Table 78	Blood pressure: number and percentage of patients with orthostatic hypotension before and during the study according to time interval by assigned treatment	494
Table 79	Body weight: summary statistics according to time interval by assigned treatment and sex	495
Table 80	Body weight: number and percentage of patients with values lower or higher than pre-treatment at each evaluation time, by assigned treatment and sex	498

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Pharmacia

Document 9550082

Table 81	ECG: number and percentage of patients with abnormal ECG according to time intervals, by assigned treatment and sex	501
Table 82	ECG: shift table - number of patients with normal or abnormal ECG value at each evaluation time as compared to pre-treatment evaluation, by assigned treatment	502
Table 83	ECG: shift table - number of patients with normal or abnormal ECG value at last assessment as compared to pre-treatment evaluation, by assigned treatment	503
Table 84	ECG: number and percentage of ECG abnormalities observed during the study, by assigned treatment	504
Table 85	ECG: shift table - number of patients with absent or present ECG abnormalities at last assessment as compared to pre-treatment evaluation, by assigned treatment	505
Table 86	ECG: number and percentage of ECG abnormalities, by abnormality group, observed during the study by assigned treatment	514
Table 87	ECG: shift table - number of patients with absent or present ECG abnormalities, by abnormality group, at last assessment as compared to pre-treatment evaluation, by assigned treatment	515
Figures		516
Figure 1	Mean decreases of HAMD total score at last assessment. Point estimates and confidence intervals	517
Figure 2	Cumulative probability of 50% decrease in HAMD total score	518
Figure 3	Severe patients judged by CGI severity at baseline. Mean decreases of Hamilton total score at last assessment. Point estimates and 95% confidence intervals	519
Figure 4	Melancholic patients. Mean decreases of HAMD total score at last assessment. Point estimates and 95% confidence intervals	520
Figure 5	Cumulative risk of developing the first adverse event during treatment	521
Figure 6	Cumulative risk of developing agitation/anxiety/nervousness	522
Figure 7	Cumulative risk of developing asthenia/fatigue	523
Figure 8	Cumulative risk of developing blurred vision	524

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Pharmacia	Document 9550082	
Figure 9	Cumulative risk of developing constipation	525
Figure 10	Cumulative risk of developing headache/migraine	526
Figure 11	Cumulative risk of developing hypotension and related symptoms	527
Figure 12	Cumulative risk of developing insomnia	528
Figure 13	Cumulative risk of developing dry mouth	529
Figure 14	Cumulative risk of developing nausea and related symptoms	530
Figure 15	Cumulative risk of developing paraesthesia	531
Figure 16	Cumulative risk of developing somnolence	532
Figure 17	Cumulative risk of developing increased sweating	533
Figure 18	Cumulative risk of developing tremor	534
Figure 19	Cumulative risk of developing urinary hesitancy/retention	535
Figure 20	Cumulative risk of developing vertigo	536
Figure 21	Percentage of patients with at least one adverse event when exposed to treatment according to time intervals	537
12.	Appendices	538
12.1	Study Information	539
12.1.1	Protocols and Protocol Amendments	540
12.1.2	CRF Sample	673
12.1.3	Ethics Committees or Investigational Review Boards: Approvals, List of Members, Patient Information and Consent Forms	674
12.1.4	Clinical Investigators List, Signatures and Curricula Vitae	675
12.1.5	Certificates of Analysis	679
12.1.6	Audit Certificate	693
12.1.7	Randomisation List	695

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Pharmacia

Document 9550082

12.1.8	Criteria Used to Judge Laboratory Abnormalities as Clinically Relevant and Reference Values for Laboratory Tests	716
12.1.9	Adverse Events Grouped in Clusters	719
12.1.10	ECG Codes	722
12.1.11	Statistical Analysis Programs Listings	724
12.1.12	Selection of Statistical Analysis Outputs	733
12.2	Patient Information	817
12.2.1	Serious Adverse Events - Case Histories	818
12.2.2	Individual Data Listings	825
Listing 1.0	Patient Identification	826
Listing 2.0	History of Mental Disorder and Present Episode	835
Listing 3.0	DSM-III-R: Diagnostic Criteria for the Major Depressive Episode	844
Listing 4.0	Medical History and Admission Examination Findings	854
Listing 5.0	Chest X-Ray	862
Listing 6.0	Previous Antidepressive Treatment	882
Listing 6.1	Duration of Drug-Free Wash-Out Period	894
Listing 7.0	Inclusion/Exclusion Criteria	916
Listing 8.0	Concomitant Drugs	959
Listing 9.0	Experimental Treatment: Daily Dose and Cumulative Compliance Experimental Treatment: Daily and Cumulative Compliance	980
Listing 10.0	Assigned vs Randomised Treatment	1064
Listing 11.0	Reasons for Discontinuation of the Treatment	1073
Listing 12.0	Hamilton Depression Rating Scale	1094
Listing 12.1	Hamilton Depression Rating Scale: Factors and Total Score	1251
Listing 13.0	Montgomery and Asberg Depression Rating Scale	1310

Pharmacia		Document 9550082
Listing 14.0	Relational Depression Rating Scale	1397
Listing 16.0	Clinical Global Impression	1495
Listing 17.0	Adverse Events: Detail and Summary	1538
Listing 18.0	Laboratory Data	1623
Listing 19.0	Urinalysis	1968
Listing 20.0	Vital Signs and Assessment Dates	2001
Listing 21.0	ECG Tracings	2064
12.2.3	CRFs	2095

LIST OF ABBREVIATIONS AND TERMS

ANOVA	analysis of variance
AUC	area under the curve
b.i.d.	twice daily
BUN	blood urea nitrogen
CGI	clinical global impression
C.I.	confidence interval
CRF	case record form
DMI	desipramine
DSM-III-R	diagnostic and statistical manual - third edition - revised
ECG	electrocardiogram
ECT	electroconvulsive therapy
EI	efficacy index
gamma GT	gamma glutamyl transpeptidase
GCP	Good Clinical Practice
HAMD	Hamilton depression rating scale
IRB	Institutional Review Board
MADRS	Montgomery and Asberg depression rating scale
MMS	mini mental state
o.d.	once daily
REM	rapid eye movement
RDRS	relational depression rating scale
SD	standard deviation
SGOT	serum glutamic-oxaloacetic transaminase
SGPT	serum glutamic-pyruvic transaminase
T4	thyroxin
TSH	thyroid-stimulating hormone

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**REBOXETINE - PROTOCOL 20124/015
SYNOPSIS**

Name of Company: Pharmacia Spa Name of finished product: Name of active ingredient(s): Reboxetine	Individual study table referring to part IV of the dossier Ref.: Vol.: Page:	(For national authority use only)
Title of study: Multicentre, multinational double-blind study of the activity and tolerability of reboxetine vs imipramine and placebo in patients suffering from Major Depressive Episodes (protocol 20124/015, Report n° 9550082).		
Investigators: Dr R Gupta, Prof J Pellet, Dr JL Terra, Dr Scharbach, Dr G Leibovici, Dr RA Castiglioni, Dr Hourri, Dr M Costes, Dr JP Chabannes, Dr M Goudemand, Dr Briole, Dr JC Haxaire, Dr G Campa, Dr C Blanchard, Dr R Pagot, Prof JM Leger, Dr M Bouchard, Dr JF Charbonnier, Prof S Brion, Dr PY Cullerre, Dr B Baranowski, Dr EU Vorbach, Prof M Hummel, Prof HJ Schierle, Prof T Schmitt, Prof P Mayr, Prof J Schimek, Prof E Aguglia, Prof E Smeraldi, Prof RG Priest, Prof M Ohayon, Prof GD Burrows, Prof J Tiller, Dr T George.		
Study centres: Phillip Health Centre, Woden, Canberra, Australia; Hôpital Bellevue, St. Etienne, France; Centre Hôpitalier Spécialisé, Le Vinatier, Lyon, France; CHU Service Médico-Psycholog., Nantes, France; Avenue de la Serane, Marseille, France; Hôpital Sainte Marguerite, Service de Psychiatrie, Marseille, France; Clinique Psychiatrique du Parc, Nantes, France; Centre Hôpitalier Spécialisé, Saint Egrève, France; Centre Hôpitalier Spécialisé de Bassens, Chambéry, France; Unité de Soins Normalisés, Lille, France; Hôpital d'Instruction des Armées du Val-de-Grace, Paris, France; Bd Joffre, Nancy, France; Rue Nestor Cornier, Grenoble, France; CH, St Nazaire, France; Centre Hôpitalier Spécialisé, Saint-Ave, France; CHU - Service de Psychiatrie, Limoges, France; Centre Hôpitalier Spécialisé Gerard Marchant, Toulouse, France; Hôpital St Jacques, Clermont-Ferrand, France; Hôpital Richaud, Service de Psychiatrie, Versailles, France; Rue Colonel Jean Muller, Lorient, France; Rue de Nemours, Rennes, France; Psychiatrische Klinik, Elisabethenstift, Darmstadt, Germany; Psychiatrische Univ. Klinik, Marburg/Lahn, Germany; Puiseaux Platz, Rodgau, Germany; General Hospital, Waldbrunn-Hintermeilingen, Germany; Mozartstr, Stokach, Germany; Münchener Str., Frankfurt, Germany; Dpt. of Psychiatry, Università di Trieste, Trieste, Italy; Associazione Croce al Vallone, Biancavilla CT, Italy; Ospedale S Raffaele - Villa Turro, Milano, Italy; Academic Dpt. of Psychiatry, St Mary's Hospital, London, UK; Centre of Research, Hôpital Louis La Fontaine, Montreal, Canada; Dpt. of Psychiatry, University of Melbourne, Austin Hospital, Heidelberg, Australia; The Royal Hospital, Melbourne, Australia; The Prince Charles Hospital, Chermshire, Brisbane, Australia.		
Publication (reference): None		
Study period: January 1991 - November 1992	Clinical Phase: III	
Objectives: To assess the activity and tolerability of reboxetine in comparison with placebo and imipramine in patients suffering from Major Depressive Episodes.		
Methodology: In this prospective, double-blind, randomised, controlled, parallel group, multicentre and multinational trial, patients underwent an initial wash-out period of 4-14 days (≥ 3 weeks in the case of fluoxetine administration), after which they received reboxetine 4 mg b.i.d., imipramine 50 mg b.i.d. (Days 1-3) then imipramine 150 mg/daily (50 mg in the morning and 100 mg in the evening) (Days 4-42) or placebo b.i.d. for six weeks. At the end of the initial 3 weeks of treatment, patients could be switched to an higher dose regimen, corresponding to 10 mg/day reboxetine and 200 mg/day imipramine.		

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Document 9550082

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<p>For ethical reasons, patients willing to continue after completion of 6 weeks' treatment were provided with study medication and maintained on the same medication until the last patient recruited had completed the study and all the CRFs had been collected. The response to treatment was assessed by the investigators using the Hamilton Depression Scale (HAMD), Clinical Global Impression (CGI), the Montgomery and Asberg Depression Rating Scale (MADRS), and the Relational Depression Rating Scale (RDRS) and by the patients using the Patient Global Impression (PGI) and the Cognitive Evaluation. The results of the PGI and the Cognitive Evaluation were not evaluated due to the very low number of patients completing the assessments.</p> <p>Safety and tolerability were assessed by the reporting of any adverse events and assessment of vital signs (supine and standing blood pressure and heart rate), laboratory tests, and ECG.</p> <p>Number of subjects (planned and analysed): Three hundred and thirty patients were to be recruited in the study. Three hundred and thirty-nine patients (201 females and 138 males) from 34 centres were recruited to the study and treated with either reboxetine (112), imipramine (115) or placebo (112).</p> <p>Diagnosis and main criteria for inclusion: Patients were diagnosed according to the DSM-III-R classification. The severity of depression was evaluated using the HAMD and CGI scales. Criteria for inclusion were as follows: (1) Patients of either sex, of any race, aged 18 to 65 years, with a diagnosis of acute of Major Depressive Episodes, not accompanied by psychotic features (DSM-III-R) with the current episode having been present for 1-4 months; (2) Initial (pre-treatment) total score for the 21-item HAMD had to be ≥ 22.</p>		
<p>Test product: capsules containing RBX methanesulphonate tablets</p> <p>Unit dose: 4 mg (two 2 mg tablets) or 6 mg (three 2 mg tablets) of reboxetine (free base)</p> <p>Mode of administration: by oral route, b.i.d.</p> <p>Batch no.: 4 mg: SF1131, SF1264; 6 mg: SF1132, SF1291</p>		
<p>Duration of treatment: Double-blind phase : 6 weeks</p>		
<p>Reference therapy: Imipramine 50 mg (25 mg x 2 tablets) and 100 mg (25 mg x 4 tablets) in capsules. Placebo tablets (excipients alone) in indistinguishable capsules</p> <p>Unit Dose: 50 mg or 100 mg imipramine</p> <p>Mode of administration: by oral route b.i.d. (both imipramine and placebo)</p> <p>Batch no.: SF1130, SF1265 (imipramine 50 mg); SF1129, SF1151, SF1263 (imipramine 100 mg); SF1133, SF1247 (placebo 4 mg); SF1134, SF1306 (placebo 6 mg)</p>		
<p>Criteria for evaluation:</p> <p>Efficacy</p> <p><i>Study end-point:</i> difference of HAMD total score at last assessment vs baseline.</p> <p><i>Response:</i> HAMD total score decrease equal to or greater than 50% compared to the baseline value (Visit 0).</p> <p><i>Remission:</i> HAMD total score lower than or equal to 10 (absolute value).</p> <p><i>Time to response:</i> no. of days at onset of response confirmed at all subsequent available assessments.</p> <p>HAMD total scores and factor scores, MADRS total scores, CGI classification, RDRS total scores.</p>		

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Pharmacia

Document 9550082

<p>Name of Company: Pharmacia Spa</p> <p>Name of finished product:</p> <p>Name of active ingredient(s): Reboxetine</p>	<p>Individual study table referring to part IV of the dossier</p> <p>Ref.:</p> <p>Vol.:</p> <p>Page:</p>	<p>(For national authority use only)</p>
<p>Safety</p> <p>Reporting of adverse events, measurements of vital signs (supine and standing blood pressure and heart rate), laboratory tests, and ECG. Clinically relevant modifications of blood pressure (BP) and heart rate (HR) ($\geq 20\%$ vs baseline), or such modifications associated with critical values (≥ 160 or ≤ 100 mmHg for systolic BP; ≥ 100 or ≤ 70 mmHg for diastolic BP; ≥ 100 or ≤ 50 beats/min for HR). Orthostatic hypotension (decrease of systolic BP ≥ 30 mmHg from lying to standing). Clinically relevant changes of laboratory tests and abnormal ECG findings according to standardised criteria.</p>		
<p>Statistical Method:</p> <p>Efficacy</p> <p>Mean decreases of HAMD total score at last valid observation were analysed by one-way ANOVA, testing differences between each of the active treatments (reboxetine and imipramine) and placebo by one-tailed Dunnett's-test (overall type I error of 0.05). Secondary efficacy variables, including HAMD, MADRS and RDRS total scores and CGI, were summarised by descriptive statistics at each visit and at the last valid observation. Homogeneity of baseline HAMD total scores across treatment groups was tested by ANOVA. Homogeneity of variances was tested by Bartlett's test. Ninety-five per cent confidence intervals (two tails) of the mean difference of each treatment were computed.</p> <p>The same sets of analyses were carried out on the subset of severe (CGI-Severity of illness, markedly to extremely ill at baseline) and melancholic patients (DSM IV criteria).</p> <p>Independent Chi square tests was applied in order to compare frequency of response/remission in the three treatment groups. The cumulative probability of the onset of response (time to response) was computed adopting the Kaplan-Meier method and pairwise comparisons between each of the active treatments and placebo were carried out by log-rank test.</p> <p>Safety</p> <p>For all the laboratory tests frequency of patients shifted from values below, within or above the normal range at baseline to values below, within or above the normal range at each visit were computed. The Stuart Maxwell test was applied to test the changes in the distribution across categories at each visit vs baseline.</p> <p>Continuous values of laboratory tests were standardised according to method proposed by Chuang-Stein and Wilcoxon Rank Signed test for paired data was applied in order to compare the values during treatment with those recorded at baseline.</p> <p>The cumulative risk of developing the first adverse event, as well as individual adverse event and adverse event clusters (newly emerged in 5% or more of patients in at least one treatment group) was estimated by Kaplan-Meier method and the difference between treatments was tested by the log-rank test.</p>		
<p>Results</p> <p>Three hundred and thirty-nine patients (201 females and 138 males) were admitted to the study. A total of 252 patients (74.3%) completed the study and 87 (25.7%) withdrew (3 of them, 2 in the imipramine and 1 in the placebo group, having the last assessment at Day 42 visit): 23 (20.5%) in the reboxetine group, 38 (33.0%) in the imipramine group and 26 (23.2%) in the placebo group. Newly emerged adverse events were the main reason for treatment discontinuation in 11 (9.8%), 15 (13.0%) and 7 (6.3%) patients in the reboxetine, imipramine and placebo groups. One patient from the imipramine group died by suicide.</p>		

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Pharmacia

Document 9550082

<p>Name of Company: Pharmacia Spa</p> <p>Name of finished product:</p> <p>Name of active ingredient(s): Reboxetine</p>	<p>Individual study table referring to part IV of the dossier</p> <p>Ref.:</p> <p>Vol.:</p> <p>Page:</p>	<p>(For national authority use only)</p>
<p>Results (continued)</p> <p>Deterioration was the main reason for withdrawal in 5 (4.5%), 11 (9.6%) and 11 (9.8%) patients in the three groups, respectively. Remaining cases included mainly lost to follow up and uncooperative patients (reboxetine 5, imipramine 10 and placebo 7).</p> <p>Efficacy</p> <p>In the 110 patients randomised to reboxetine who had at least one assessment in addition to baseline, the mean HAMD total score was reduced from 27.5 at Day 0 to 14.0 at last assessment, and to 11.3 at Day 42 in the 89 patients assessed at Day 42. In the 111 patients randomised to imipramine with at least one assessment in addition to baseline, the mean HAMD total score was reduced from 26.9 at Day 0 to 13.2 at last assessment, and to 9.4 at Day 42 (79 patients). Mean HAMD total score in the 111 patients randomised to placebo was reduced from 27.1 at Day 0 to 15.8 at last assessment, and to 13.1 at Day 42 (87 patients). The between treatment difference in the decrease of HAMD total score at last assessment was not statistically significant ($p > 0.025$, one-tailed test) for both the reboxetine vs placebo and the imipramine vs placebo comparisons.</p> <p>At last assessment, 59.1% of the 110 reboxetine-treated patients, 62.2% of the 111 imipramine-treated patients and 52.3% of the 111 placebo-treated patients were classified as responders, while 42.7%, 50.5% and 36.0%, respectively, were seen to be in remission. There were no statistically significant differences between active treatments and placebo for response and remission. Patients on imipramine showed a cumulative probability of response (Kaplan-Meier method) significantly higher ($p = 0.0055$) than patients on placebo, while was not the case for the patients on reboxetine ($p = 0.081$).</p> <p>With regard to the mean decrease of the HAMD total score at last assessment in patients classified as markedly to extremely ill at admission in the three treatment groups (77 reboxetine, 80 imipramine and 69 placebo), the improvement on both active treatments is maximal and is minimal on placebo; the mean difference between active treatments was almost nihil (0.12 points, 95% C.I.: $-3.2 \div 3.4$), but the difference between active treatments and placebo reached statistical significance ($p < 0.025$) only for imipramine. For the mean decrease at last assessment of the HAMD total score in those patients which could be classified as melancholic at admission in the three treatment groups (melancholic/non-melancholic: 51/46 reboxetine, 44/53 imipramine, 41/60 placebo), the difference between active treatments and placebo reached statistical significance in the case of reboxetine, but not of imipramine. The mean difference between active treatments was in fact in favour of reboxetine with a value of 3.9 points (95% C.I.: $-0.5 \div 8.3$).</p> <p>As for the frequency distribution of CGI scores at last assessment, the clearest difference between treatments was related to the percentage of patients who were 'very much improved'; this was higher in the reboxetine group (29.1%) and the imipramine group (28.8%) compared with the placebo group (17.1%). In addition, the percentage of patients judged unchanged was higher in the placebo group (17.1%) than in the reboxetine group (9.1%) and imipramine group (10.8%). A similar pattern was observed at Day 42 in the patients who completed the study: 34.8% of the 89 reboxetine- and 39.2% of the 79 imipramine- vs 20.7% of the 87 placebo-treated patients were judged very much improved.</p> <p>The mean total MADRS score was reduced from 16.4 at Day 0 to 8.4 at last assessment in the 110 reboxetine group patients with at least one assessment in addition to baseline, and to 6.6 at Day 42 in the 89 reboxetine patients assessed. In patients randomised to imipramine, values changed from 16.7 at Day 0 to 8.2 at last assessment (111 patients), and to 5.8 at Day 42 (79 patients). The corresponding reductions in placebo group patients were from 16.3 at Day 0 to 9.8 at last assessment (111 patients) and to 7.7 at Day 42 (87 patients).</p>		

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Pharmacia

Document 9550082

<p>Name of Company: Pharmacia Spa</p> <p>Name of finished product:</p> <p>Name of active ingredient(s): Reboxetine</p>	<p>Individual study table referring to part IV of the dossier</p> <p>Ref.:</p> <p>Vol.:</p> <p>Page:</p>	<p>(For national authority use only)</p>
<p>Efficacy (continued)</p> <p>The mean total RDRS score was reduced from 18.8 at Day 0 to 9.6 at last assessment in the 109 reboxetine group patients with at least one assessment in addition to baseline, and to 7.6 at Day 42 (88 patients). In patients randomised to imipramine, values changed from 18.6 at Day 0 to 9.1 at last assessment (111 patients), and to 6.5 at Day 42 (79 patients). The corresponding reductions in placebo group patients were from 18.0 at Day 0 to 11.1 at last assessment (111 patients) and to 9.4 at Day 42 (87 patients).</p> <p>Safety</p> <p>All the 339 patients who received study treatment were included in the safety analysis (112 reboxetine, 115 imipramine, 112 placebo). For clinical and laboratory tests were analysed only patients with at least one assessment in addition to baseline.</p> <p>During the study, the occurrence of newly reported adverse events was higher in the imipramine group than in the reboxetine or placebo groups; 71/112 (63%) reboxetine group patients reported 211 adverse events compared with 81/115 (70%) imipramine patients who reported 288 adverse events and 58/112 placebo group (52%) patients who reported 141 adverse events. Compared to placebo the cumulative risk of occurrence of adverse events (Kaplan Meier) was significantly higher on imipramine ($p = 0.001$) and approaches significance for reboxetine ($p = 0.051$).</p> <p>Most frequently reported were: dry mouth (25.0% reboxetine, 42.6% imipramine and 12.5% placebo); constipation (15.2%, 15.7%, 5.4%) and increased sweating (12.5%, 19.1%, 2.7%). In addition, events reported with different frequencies in the three groups were: insomnia (11% on reboxetine, 7% on imipramine, 4% on placebo), vertigo (5% and 6% on reboxetine and imipramine, 0% on placebo), tremor (5% on reboxetine and placebo, 17% on imipramine), hypotension and related symptoms (9% on reboxetine, 17% on imipramine, 5% on placebo) blurred vision (9% on imipramine, 5% on reboxetine, 3% on placebo). The majority of adverse events were moderate in all treatment groups. Adverse events were reported with a similar frequency by women and men in all treatment groups. As for individual events or clusters the most relevant between-gender differences were noticed in all treatment groups and were related to the frequency of dry mouth, constipation, increased sweating, and nausea and related symptoms, complained of mainly by female patients.</p> <p>As for individual events or clusters, the cumulative risk was significantly higher on reboxetine than on placebo for insomnia, increased sweating, dry mouth, vertigo and constipation. Similarly, the cumulative risk was significantly higher on imipramine than on placebo for dry mouth, constipation, increased sweating, vertigo, hypotension and related symptoms, tremor and blurred vision. The direct comparison between reboxetine and imipramine is in favour of reboxetine for dry mouth, hypotension and related symptoms and tremor.</p> <p>There were one death (suicide) in the imipramine group and 5 cases of serious adverse events, all occurred in the imipramine- and placebo-treated patients: 2 cases of attempted suicide occurred in the placebo group, while 1 case of attempted suicide, 1 case of postural hypotension, dizziness and syncope and 1 case of attention seeking autolesionistic behaviour in the imipramine group.</p> <p>There was no indication of modifications in laboratory tests that were of clinical significance.</p> <p>Vital signs were not modified to any significant extent with the exception of heart rate, which more frequently increased to clinically significant values in the reboxetine (up to 12% of the patients) and imipramine (up to 8% of the patients) groups compared to placebo (up to 2% of the patients)</p> <p>No indication of effect on cardiac function emerged from ECG recordings.</p>		

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Pharmacia

Document 9550082

Name of Company: Pharmacia Spa Name of finished product: Name of active ingredient(s): Reboxetine	Individual study table referring to part IV of the dossier Ref.: Vol.: Page:	(For national authority use only)
Conclusions: The results of the statistical analysis of the study end-point do not allow the refusal of the null hypothesis of no difference between both active treatments and placebo. However, indications on the higher efficacy of active treatments compared to placebo derive from the analysis of the cumulative rate of response in the total population, particularly in the case of imipramine, and from the sub-population analyses in severe and melancholic patients, for both reboxetine and imipramine. The safety profiles of reboxetine and imipramine, compared to placebo, were similar with regard to vital signs, haematology and blood chemistry tests and ECG examinations. The cumulative risk of adverse events according to the Kaplan-Meier method and log-rank test was significantly higher on imipramine compared to placebo and approached significance on reboxetine compared with placebo. As for individual events, the cumulative risk was higher on reboxetine (as well as on imipramine) than on placebo for dry mouth, increased sweating, constipation and vertigo, while it was higher on reboxetine (but not on imipramine) than on placebo for insomnia. The direct comparison between reboxetine and imipramine in terms of increased risk of adverse events indicated significant differences always in favour of reboxetine (dry mouth, hypotension and related symptoms and tremor).		

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1. INTRODUCTION

Reboxetine (FCE 20124 or (2RS, α RS)-2-[α -(2-ethoxy-phenoxy) benzyl] morpholine) is a new chemical compound which is highly potent in the pharmacological and biochemical tests predictive of antidepressant efficacy such as reserpine antagonism, norepinephrine reuptake inhibition and REM sleep latency increase [1]. Reboxetine also demonstrates the ability to prevent the effects of clonidine after a single oral dose in an animal model, where tricyclic antidepressants were active only upon repeated administration [1]. Therefore, reboxetine was hypothesised to exert antidepressant efficacy of faster onset than the antidepressants currently available in depressed patients. In addition, comparison with imipramine 75 mg in healthy volunteers [2, 3] revealed that reboxetine does not possess the marked sedative activity of imipramine, but rather psychostimulating properties.

Pharmacokinetic studies in healthy volunteers [4], showed that average peak reboxetine levels were observed at 2 hours after oral administration, with remarkably stable levels 1-6 hours after administration; its plasma half-life was estimated as 13.2 hours and 73% of the AUC following an oral dose was accounted for by unchanged reboxetine.

An early phase II, 4-week, multicentre study in 98 patients in which reboxetine was administered at fixed changing doses, with maximum doses of 4 and 12 mg, showed that it was well tolerated at doses of up to 10 mg/day [5].

A double-blind, parallel groups, multicentre study in 258 patients hospitalised due to a major depressive episode compared maximum doses of 8 mg reboxetine with 200 mg of desipramine and placebo over a period of 4 weeks [6]. Reboxetine was found to be more effective than placebo with decreases of $\geq 50\%$ in Hamilton Depression Rating Scale (HAMD) at the end of treatment in 63% of patients compared with 36% for placebo and 46% for desipramine. These decreases were present after 14 days of treatment in 31% of reboxetine patients and 22% of desipramine patients. More reboxetine patients complained of headache and urinary retention, whereas more desipramine patients experienced dry mouth, sweating and blurred vision. Cardiovascular adverse events were relatively rare, but appeared with slightly higher frequency in the desipramine group (hypotension and tachycardia).

Phase II results obtained in controlled conditions in patients suffering from major depressive disorders indicate that reboxetine is an effective antidepressant agent with a favourable therapeutic index with respect to desipramine. The present study was designed to extend information obtained from other placebo-controlled studies and to collect comparative evidence of reboxetine's safety and efficacy vs a tricyclic antidepressant [7]. A comparison of reboxetine with imipramine was expected to provide a proper appraisal of the activity and tolerability of reboxetine.

2. STUDY OBJECTIVES

To assess the activity and tolerability of reboxetine in comparison with placebo and imipramine in patients suffering from major depressive episodes.

3. INVESTIGATIONAL PLAN

3.1 Study Design and Plan - Description and Rationale

3.1.1 OVERVIEW AND JUSTIFICATION

This phase III study was designed as a prospective, double-blind, randomised, controlled, parallel-group, multicentre trial. Its aim was to compare the efficacy and tolerability of reboxetine with that of imipramine and of placebo, administered orally for 6 weeks, in adult patients with major depressive episodes. The design of the study is shown overleaf.

A total of 330 patients with major depressive episodes was to be recruited in accordance with the inclusion and exclusion criteria, and an informed consent obtained from each patient prior to screening.

At screening, a full medical history and physical examination (including chest X-ray and electrocardiogram (ECG)) were carried out and vital signs and laboratory values were measured. Patients were classified according to the DSM-III-R classification and the severity of depression was evaluated using the Hamilton Depression Rating Scale (HAMD) and Mini Mental State (MMS) examination.

After an initial wash-out period of 4-14 days (14 days in the case of monoamine oxidase inhibitors administration and 3-4 weeks in the case of fluoxetine treatment), patients received one of 3 treatments: oral reboxetine 4 mg b.i.d., oral imipramine 50 mg b.i.d. (Days 1-3) then 50 mg in the morning and 100 mg in the evening (Days 4-42), or placebo b.i.d. for 6 weeks. In the case of inefficacy or unsatisfactory response, combined with good tolerability, after 3 weeks of treatment, the total daily dose was allowed to be increased to 10 mg for reboxetine (4 mg in the morning and 6 mg in the evening) and 200 mg (100 mg b.i.d.) for imipramine for the remaining 3 weeks of the study.

The primary study end-point was defined as the HAMD total score difference vs Day 0 at last assessment. Response (a decrease of at least 50% in the total HAMD score) and remission (a total HAMD score of 10 or less) were considered to be additional study end-points and their rates at last assessments were also to be compared statistically between treatment groups.

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Document 9550082

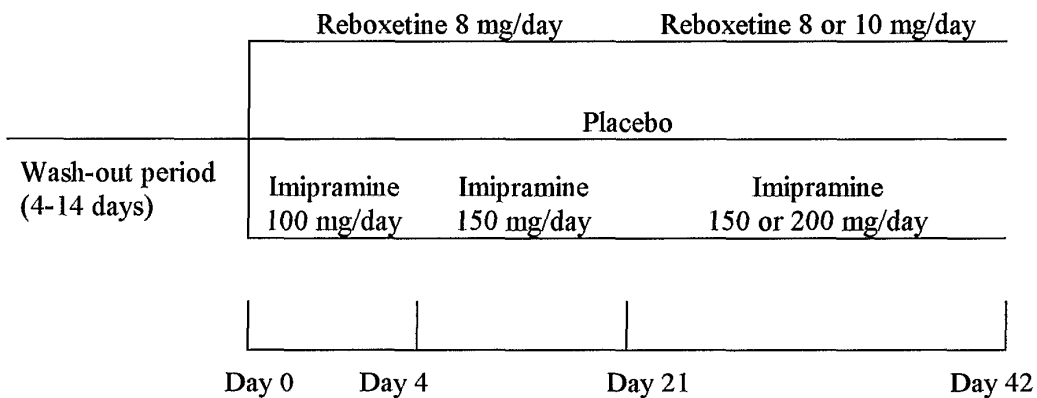
Other variables used for evaluating efficacy were the Clinical Global Impression (CGI), the Montgomery and Asberg Depression Rating Scale (MADRS), Patient Global Impression (PGI) Scale, the Relational Depression Rating Scale (RDRS) and cognitive evaluation.

Safety and tolerability were assessed by the reporting of any adverse events and measurements of vital signs (blood pressure and heart rate (supine and standing)), ECG and laboratory tests.

For ethical reasons, patients willing to continue receiving the test treatment after completion of the 6 weeks' treatment period were provided with study medication and maintained on the same medication under blind conditions until the completion of the last patient in the study and collection of the Case Record Forms (CRFs).

A follow-up visit was to be carried out for each patient one month after treatment discontinuation, in order to monitor possible withdrawal reactions and collect information on any events since treatment discontinuation.

A copy of the final protocol can be found in Appendix 12.1.1. A modified protocol used in the Canadian centre is also included.



3.1.2 PROTOCOL AMENDMENTS

There were three protocol amendments. The first one extended the wash-out period to 3-4 weeks in case of previous fluoxetine administration. The second ones were requested by different countries' ethical committees (France, Australia, Germany and Canada) In the French country the amendment specified that the patient and the investigator should sign the consent form. If the patient was not able to give his or her consent, the signature of the next of kin was to testify that full information was given to the patient; in the Australian

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Document 9550082

country it replaced chloral hydrate with short acting benzodiazepines (e.g. temazepam 10 mg) as a permitted sleep inducer at bed-time and in the German and Canadian countries it specified that the exclusion criteria "High risk of suicide" had to correspond to a score "3" or "4" in the HAMD scale item 3 "Suicide".

A modified version of the protocol was used in the Canadian centre: here in fact, only the patients with a total score of 22 or above in the first 17 items of the 21-HAMD were to be included in the study, while all the patients in whom the use of any psychotropic agent could not be removed during the entire experimental study were to be excluded, as well as the patients with a clinical improvement at the end of the wash-out period (decrease of the HAMD of at least 1 point).

3.2 Ethics

3.2.1 ETHICS COMMITTEE

Approval from the Ethics Committees or Institutional Review Boards (IRBs) of the participating centres, in accordance with the regulations and requirements of individual countries, had to be obtained before the study could be undertaken. It was the responsibility of each of the investigators to submit the study protocol with its attachments to the Ethics Committee/IRB. A central approval allowing the clinical evaluation of the product was required and obtained in Italy, Australia and UK, and local approvals were required and obtained in France, Germany, Italy, UK and Australia.

The Central/IRB notifications of approval are kept in the trial master file.

The written approval of the Ethics Committee or IRB had to include the names and professions of all its members. In accordance with local requirements, the investigators were responsible for informing the Ethics Committees of any emergent problems, serious adverse events or protocol amendments.

3.2.2 PATIENT INFORMATION

Before entering the study, an explanation of the nature, duration, purpose of the study and action of the compound had to be given to each patient, in such a manner that he/she was made aware of the potential risks, inconveniences or adverse events that could occur, and could express his/her informed consent to participation. The proposed consent form is enclosed (Enclosure 3 of Appendix 12.1.1). The translations in the national languages and the individual centres forms containing the possible changes requested by the Ethics Committees, if any, are kept in the study master file. The forms were signed by the patient or the next of kin, and/or the investigator. In the latter case, the signature of a witness was required to testify that full information was given to the patient.

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Document 9550082

All unpublished documentation including the protocol, the CRF and the Investigator's Brochure was confidential. These documents could not be disclosed to a third party without the written consent of the Sponsor. The submission of these documents to the Ethics Committee was expressly permitted. The investigators agreed that the Sponsor maintained the right to utilise the results of this study, in their original form and/or in a global report, for submission to the governmental and regulatory authorities of any country.

3.3 Study Population

Adult patients who were under in-patient care or attending out-patient or day-hospital clinics of the participating centres were selected in accordance with the following inclusion and exclusion criteria.

3.3.1 INCLUSION CRITERIA

The criteria for participation in this study were as follows:

- Patients of either sex, of any race, aged 18 to 65 years
- A diagnosis of acute major depressive episodes, not accompanied by psychotic features (DSM-III-R) [8]; the current episode was to have been present for at least one month but no more than 4 months
- The initial (pre-treatment) total score for the 21-item HAMD [9] had to be ≥ 22 . In the Canadian centre, a total score of ≥ 22 in the first 17 items of the 21-item HAMD was required
- Informed consent was obtained from the patient or next of kin, and/or the investigator (see Section 3.2.2)

3.3.2 EXCLUSION CRITERIA

Exclusion criteria for patients recruited to this study were as follows:

- Dysthymia/cyclothymia
- History of major depressive disorder associated with endocrine disorders: hypo- or hyperthyroidism (defined as values at least 10% outside normal tests for TSH and T₄), adrenal insufficiency, etc.
- Pregnancy (excluded by a pregnancy test at the end of the wash-out period)

Pharmacia

Document 9550082

- Refusal by female patients of childbearing age to use effective contraception during the study period
- Past history of drug hypersensitivity
- Participation in a clinical study with an investigational compound in the 4 weeks preceding the study
- Evidence of Substance Use Disorder (DSM-III-R), currently or within the past 6 months
- Chronic respiratory insufficiency (excluded by physical examination and X-ray)
- History or presence of gastrointestinal, hepatic or renal disease, or other conditions known to interfere with the absorption, distribution, metabolism and excretion of drugs
- History of seizures or brain injury; current evidence of clinically important haematopoietic or cardiovascular diseases; current evidence of urinary retention or glaucoma
- Symptoms of any other important clinical illness in the 4 weeks preceding the study
- Clinically relevant abnormal findings in the physical examination, laboratory tests and ECG at admission
- MMS score <22 (Enclosures 4 and 6 of Appendix 12.1.1)
- Electroconvulsive therapy (ECT) in the previous 3 months
- High risk of suicide

In the Canadian centre, the final exclusion criterion was modified to "risk of suicide" and there were two additional exclusion criteria:

- Use of any psychotropic agent which cannot be removed during the entire experimental study
- Clinical improvement at the end of the wash-out period (decrease of the HAMD of at least one point)

3.3.3 WITHDRAWAL CRITERIA

Patients could be withdrawn from the study at any time for the following reasons:

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Document 9550082

- Voluntary withdrawal by the patient
- Unacceptable toxicity, defined as the occurrence of serious adverse events (see Section 3.6.2.1)
- Lack of efficacy, defined as patients who showed worsening of the global clinical picture (CGI - see Section 3.6.1.2) after at least 2 weeks of treatment
- Shift to mania

In the case of treatment discontinuation, the final set of tests was carried out wherever possible.

3.3.4 SAMPLE SIZE - NUMBER OF PATIENTS PLANNED

Each of the planned centres participating in the study were to recruit, within a period of one year, a sample of 24-42 patients, so that a total of 330 patients was to be recruited overall.

In fact, several of the centres which initially agreed to participate in the study never did so for logistical reasons, and were replaced with other centres. As shown in the Clinical Investigators List (Appendix 12.1.4), 34 centres located in 6 countries (Australia, France, Germany, Italy, UK, and Canada) participated in the study. In 33 of these centres the number of patients admitted was lower than twenty-four. Recruitment was stopped after randomisation of 339 patients.

Patients who dropped out of the study for any reason were not substituted. For those patients selected for the study who dropped out at any time, even before entrance to the treatment period, documentation was provided.

3.4 Treatments

3.4.1 TREATMENTS TO BE COMPARED

After an initial wash-out period of 4-7 days (14 days in the case of monoamine oxidase inhibitors administration and 3-4 weeks in the case of previous fluoxetine treatment) patients received one of 3 possible treatments for 6 weeks: oral reboxetine 4 mg b.i.d., oral imipramine 50 mg b.i.d. (Days 1-3) then 50 mg in the morning and 100 mg in the evening (Days 4-42), or placebo b.i.d.. In the case of inefficacy or unsatisfactory response, combined with good tolerability, after 3 weeks of treatment, the total daily dose was increased to 10 mg for reboxetine (4 mg in the morning and 6 mg in the evening) and 200 mg (100 mg b.i.d.) for imipramine for the remaining 3 weeks of the study.

3.4.2 IDENTITY OF TEST TREATMENTS

Indistinguishable capsules containing either reboxetine 4 mg (2 x 2 mg tablets) or 6 mg (3 x 2 mg tablets) (Batch No: 4 mg: SF1131, SF1264; 6 mg: SF1132, SF1291) or imipramine 50 mg (2 x 25 mg tablets) or 100 mg (4 x 25 mg tablets) (Batch No: 50 mg: SF1130, SF1265; 100 mg: SF1129, SF1151, SF1263) plus excipients or excipients only (placebo, Batch No: 4 mg: SF1133, SF1246; 6 mg: SF1134, SF1306) were supplied by the Sponsor. Copies of certificates of analysis for the test treatments are presented in Appendix 12.1.5.

3.4.3 DOSE SELECTION AND TIMING

All patients recruited for the study received either one capsule of reboxetine 4 mg b.i.d. (morning and evening), one capsule of imipramine 50 mg b.i.d. (morning and evening) on Days 1-3 then one capsule of imipramine 50 mg o.d. (morning) and one of 100 mg o.d. (evening) on Days 4-42, or placebo b.i.d. (morning and evening) for 6 weeks. For patients who showed an ineffective or unsatisfactory response (worsening, no change or minimal improvement in the CGI; see Section 3.6.1.2) with good tolerability (especially non-symptomatic hypotension) after 3 weeks of treatment, the dose of reboxetine was increased to 10 mg daily (4 mg in the morning and 6 mg in the evening) and the daily dose of imipramine increased to 200 mg (100 mg b.i.d.), for the remaining 3 weeks of the study. In those patients who then displayed poor tolerance at this increased dose, the dose was reduced to the previously well-tolerated level.

The treatment was administered at least 2 hours before or after meals.

The daily dose of reboxetine was chosen on the basis of the results of the previously mentioned open-dose finding study [5], in which daily doses of 8 to 10 mg were found to be associated with the best therapeutic index, and of the controlled phase II study *vs* Desipramine (DMI) and placebo [6], where the 8 mg/day dose regimen was proved to possess antidepressant efficacy. The daily dose of imipramine was selected on the basis of published evidence from controlled studies [7].

3.4.4 METHOD OF ASSIGNING PATIENTS TO TREATMENT GROUPS

A randomisation list balanced within each centre and every 6 assignments was originally generated for patient allocation to either reboxetine, imipramine or placebo. In this list, in order to make the patient unequivocally identified across centres by his assignment number, a progressive number from 1 to 582 was generated. The randomisation list was prepared by Biometrics and Data Management Dept. Milano by SAS proc plan, version 5.18-6.06 and kept in a safe place until the conclusion of data clean up procedure. The test treatments were labelled according to the randomisation sequence number. Each randomised patient

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Document 9550082

was then identified by the corresponding treatment number. In spite of the anticipated break down by centre of such a sequential list, in order to minimise the waste of drug supply, the latter was shipped to the centres by full blocks of six treatments each.

Patient allocation to treatment was done by the principal investigator at the end of the wash-out period, on the basis of the patient's time of entry into the study and on the available treatment blocks.

3.4.5 TREATMENT SUPPLY AND BLINDING

To ensure the double-blind nature of the study, indistinguishable test treatment in identical cartons was to be identified using double labels indicating the protocol number, patient number, treatment period, batch number and expiry date (Enclosure 5 of Appendix 12.1.1). The detachable half of the label was to be included in the appropriate place in the CRF.

Six cartons showing the patient number and the appropriate week of treatment (Week 1-6) were prepared for each patient. Each carton contained the medication necessary for 1 week of treatment (i.e. 16 capsules, one capsule b.i.d. and 2 additional capsules for possible losses). Additional 3 cartons showing the patient number, the appropriate week of treatment (Week 4-6) and the level of dosage (dose 2) were prepared for each patient in case of possible dosage increases during the last 3 weeks of the study.

3.5 Treatment Procedures

The investigators were given individual sealed envelopes containing the information on patient's treatment, and these were to be opened only in case of emergency necessitating treatment identification. In the event of an emergency, the investigators were to notify the study monitor immediately (within 24 hours), and were to report a full description of the reasons for opening the code on the adverse event form in the CRF. The sealed individual codes were to be returned to the Sponsor at the end of the study.

3.5.1 CONCOMITANT THERAPY

With the exception of hypnotics used for sleep induction on an 'as required' basis, no concomitant medication was allowed on entry to the study. In the case of events arising during the course of the study, non-psychotropic medications which were considered necessary for the patient's welfare could be administered and were not considered protocol violations. The medication, dosage and frequency of administration was recorded on the CRF. Chloral hydrate (0.5-1 g) (or Temazepam 10 mg in the Canadian centre) was permitted at bed-time as a sleep inducer on an 'as required' basis.

3.5.2 TREATMENT ACCOUNTABILITY AND COMPLIANCE

All drug supplies were handled under the direct responsibility of the investigators and held by the Hospital Pharmacy. The study monitors checked drug storage conditions during site visits.

The investigators were responsible for drug accountability and kept a record of the test compounds received from the Sponsor, as well as the drugs dispensed to each patient on the occasion of each visit. The upper label from each of the weekly cartons dispensed to each patient was detached and fixed in the appropriate space in the CRF. On the same occasion, cartons of the previous supply were returned by the patient. These used cartons were returned to the study monitors during site visits. All unused medication was to be returned to the Sponsor at the end of the study.

3.6 Efficacy and Safety Variables

At screening, a full medical history and physical examination (including chest X-ray and ECG) were carried out and vital signs and laboratory values were measured. Patients were classified according to the DSM-III-R classification and the severity of depression was evaluated using the HAMD scale and MMS.

3.6.1 EFFICACY

Every randomised patient with at least one assessment in addition to baseline was evaluable for efficacy analysis.

Patients were seen at regular intervals throughout the study and the following efficacy assessments carried out at the specified intervals. All psychiatric evaluations and ratings were to be carried out by the same observer for a given patient and in the same setting and at the same time of day if possible.

3.6.1.1 Hamilton Depression Rating Scale

The severity of depression was evaluated using the HAMD at screening, and on Days 0, 7, 14, 21, 28, 35 and 42.

The HAMD scale [9] contained 21 items, each of which was scored (0-2, 0-3 or 0-4) to reflect whether the symptom was absent, trivial, mild, moderate or severe. Some of the items were more heavily weighted than others. The scores for all the symptoms were added together to give a global judgement of the severity of the depression.

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A decrease of at least 50% in the total HAMD score compared with Day 0 was considered to be an **index of response**, whereas a total HAMD score of 10 or less was considered an **index of remission**.

The 21-item list of the HAMD used in this study is as follows:

	<u>Item</u>	<u>Score range</u>	<u>Factor</u>
1.	Depressed mood	(0-4)	V
2.	Feelings of guilt	(0-4)	III
3.	Suicide	(0-4)	III
4.	Insomnia early	(0-2)	VI
5.	Insomnia middle	(0-2)	VI
6.	Insomnia late	(0-2)	VI
7.	Work and activities	(0-4)	V
8.	Retardation	(0-4)	V
9.	Agitation	(0-4)	III
10.	Anxiety (psychic)	(0-4)	I
11.	Anxiety (somatic)	(0-4)	I
12.	Somatic symptoms gastrointestinal	(0-2)	I
13.	Somatic symptoms general	(0-2)	I
14.	Genital symptoms	(0-2)	V
15.	Hypochondriasis	(0-4)	I
16.	Loss of weight	(0-3)	II
17.	Insight	(0-2)	I
18.	Diurnal variation	(0-2)	IV
19.	Depersonalisation and derealisation	(0-4)	III
20.	Paranoid symptoms	(0-3)	III
21.	Obsessional symptoms	(0-2)	III

More detailed definitions of the items included in the scale can be found in Enclosure 7 of Appendix 12.1.1.

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Document 9550082

Factorialisation was carried out according to the ECDEU manual [10], to yield 6 factors: Anxiety/somatisation (I), Weight (II), Cognitive Disturbances (III), Diurnal Variation (IV), Retardation (V), Sleep Disturbances (VI).

3.6.1.2 Clinical Global Impression

Severity of illness was assessed by the investigator, using the CGI [10], on Days 0, 7, 14, 21, 28, 35 and 42. The following scale was used:

1. = normal, not at all ill
2. = borderline mentally ill
3. = mildly ill
4. = moderately ill
5. = markedly ill
6. = severely ill
7. = amongst the most extremely ill patients

The investigator also evaluated the effect of treatment at each visit, with reference to the patients' condition at the start of the study, according to the following scale:

1. = very much improved
2. = much improved
3. = minimally improved
4. = no change
5. = minimally worse
6. = much worse
7. = very much worse

An Efficacy Index was then assessed by the investigators described in [10], as the ratio between the objective evaluation of improvement, scored from 1 (unchanged or worsened) to 4 (marked improvement) and the subjective evaluation of tolerability, scored from 1 (no side-effects) to 4 (side-effects outweigh therapeutic effect). The Efficacy Index score

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ranges from 0.25 (no global benefit) to 4 (maximal global benefit). Details of the Efficacy Index can be found in Enclosure 8 of Appendix 12.1.1.

3.6.1.3 Montgomery and Asberg Depression Rating Scale

The MADRS [11] was measured on Days 0, 7, 14, 21, 28, 35 and 42.

This scale consists of ten items relating to depression, selected from the 67 items in the Comprehensive Psychiatric Rating Scale [12]. The items contained in the MADRS were selected on the grounds that they were sensitive to change. The 10 items were as follows:

1. Reported sadness
2. Inner tension
3. Apparent sadness
4. Suicidal thoughts
5. Inertia
6. Inability to feel
7. Pessimistic thoughts
8. Concentration difficulties
9. Reduced sleep
10. Reduced appetite

The scale requires a structured interview for completion. A score of 0 to 3 for each item was used as in reference 12. In a proportion of cases (approximately 29.6% of the total sample) a score of 0 to 6 was used, as in reference 11. Data have been pooled by dividing by two item scores of the latter sample.

More detailed definitions of the items included in the scale can be found in Enclosure 9 of Appendix 12.1.1.

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3.6.1.4 Patient Global Impression Scale

Each patient had to complete a visual analogue scale, indicating his or her general condition on Days 7, 14, 21, 28, 35 and 42. The results collected were not evaluated due to the very low number of patients completing the assessments.

3.6.1.5 Relational Depression Rating Scale

The relational aspects of depression were explored using the RDRS on Days 0, 7, 14, 21, 28, 35 and 42 (Enclosure 11 of Appendix 12.1.1). The investigators used their judgement to propose one or two additional items of relevance for each patient. The consistency of their suggestions was evaluated and an international scale was in development.

3.6.1.6 Cognitive Function Evaluation

Cognitive function was evaluated on Days 0, 14 and 42. Details of the cognitive function tests are provided in Appendix No 1 of Appendix 12.1.1. The results collected were not evaluated due to the very low number of patients completing the assessments.

3.6.2 SAFETY

Every patient who received one dose of test treatment was included in the safety evaluation. For clinical and laboratory tests, only patients with at least one assessment in addition to baseline were analysed.

3.6.2.1 Adverse Events

Spontaneously reported

Patients were notified of any possible adverse events they might experience and were instructed to report any such adverse event to the investigators immediately.

The occurrence of adverse events was recorded on Days 0, 7, 14, 21, 28, 35 and 42.

Any newly observed sign or symptom (including clinically relevant laboratory abnormalities), noticed by the investigators or reported by the patients were reported, regardless of presumed relationship to the study medication, in the appropriate section of the CRF (Adverse Event Report Form - Enclosure 14 of Appendix 12.1.1).

For each adverse event, the following information was entered in the CRF: description, date of onset, date of stopping, severity, drug cause-effect relationship, outcome, effect of withdrawal of treatment and rechallenge. The investigators also had to note if the double-

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blind code had been broken, the action taken regarding the test drug (none, dose reduced or discontinued) and any treatment given as a result of the adverse event.

Severity was coded as follows:

1. = mild - awareness of sign or symptom, but easily tolerated
2. = moderate - discomfort enough to cause interference with usual activity
3. = severe - incapacitating with inability to work or do usual activity
4. = unknown

Relationship to test drug was coded as definite, probable, possible, doubtful, unknown or not related, according to Karch and Lasagna modified criteria [13], as shown also in Enclosure 13 of Appendix 12.1.1.

All serious* and/or unexpected** adverse events had to be reported to study monitors immediately (within 24 hours), and the details recorded on an Adverse Event Report Form. **Serious adverse event** was defined as any experience that was (potentially) fatal or life-threatening, disabling, incapacitating, requiring inpatient hospitalisation, causing a congenital anomaly or cancer, or due to an overdose. **Unexpected adverse event** was defined as any adverse experience that was not identified in nature, severity or frequency in the current Investigator's Brochure for the study.

The same procedure applied for all patients who died during the course of the study or within 30 days of completion, irrespective of whether the event was judged as related to treatment. If an autopsy was performed, a copy of the pathological report was to be sent to the Sponsor.

Adverse events reported through a check-list

The presence or absence of selected adverse events was noted through a check-list especially designed for the notification of events frequently reported in patients on antidepressant medication. The check-list is shown in Enclosure 12 of Appendix 12.1.1. These events could be either reported by the patient or observed by the investigator.

* Code of Federal Regulation, Vol. 21, Part 312. Revised as of April 1 1987, page 75.

** Bem JL, Breckenridge AM, Mann RD, Rawlins MD: Review of yellow cards (1986): report to the Committee on the Safety of Medicines. Br J Clin Pharmac 1988; 26: 679-689.

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Document 9550082

For each adverse event, the same procedure as for spontaneously reported adverse events was followed in terms of recording of information in the CRF (Adverse Event Report Form) and reporting of the 'serious' or 'unexpected' adverse event to the Sponsor.

3.6.2.2 Clinical and Laboratory Tests

Vital signs

Body weight and temperature, as well as blood pressure and heart rate (supine and standing) were measured at screening, and on Days 0, 7, 14, 21, 28, 35 and 42.

Supine blood pressure and heart rate were measured in the morning after 5 minutes in the supine position and standing blood pressure and heart rate were measured 1 to 2 minutes after standing up.

EKG

An ECG was recorded at screening, on Days 21 and 42.

Laboratory tests

Laboratory tests were recorded at screening, on Days 21 and 42.

The laboratory tests comprised the following: full blood count, serum electrolytes, liver enzymes, urinalysis, blood sugar, serum alkaline phosphatase, blood urea nitrogen (BUN), serum creatinine, uric acid, total and direct bilirubin, total serum protein and electrophoresis, serum cholesterol and triglycerides, and at screening only, TSH and T₄.

For patients who withdrew prematurely for any reason, all the assessments, including vital signs, ECG and laboratory tests, were to be performed.

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3.7 Study Procedures and Flow Chart

3.7.1 SCHEDULE OF ASSESSMENTS

Assessment	Pre-Treatment Screening	Treatment Day						
		0	7	14	21	28	35	42
Diagnosis: DSM-III-R	x							
Medical history	x							
Physical examination	x							
MMS	x							
Chest X-ray	x							
ECG	x				x			x
Laboratory tests	x				x			x
Vital signs	x	x	x	x	x	x	x	x
21-item HAMD	x	x	x	x	x	x	x	x
CGI		x	x	x	x	x	x	x
MADRS		x	x	x	x	x	x	x
PGI			x	x	x	x	x	x
RDRS		x	x	x	x	x	x	x
Cognitive evaluation		x		x				x
Compliance check			x	x	x	x	x	x
Dispensing medication		x	x	x	x	x	x	
Adverse events		x	x	x	x	x	x	x

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3.7.2 PROCEDURES AT EACH VISIT

At screening, a full medical history and physical examination (including chest X-ray and ECG) were carried out and vital signs and laboratory values were measured. Patients were classified according to DSM-III-R and the severity of depression was evaluated using the HAMD scale and MMS.

One month after treatment discontinuation, a follow-up visit was carried out for each patient, in order to monitor possible withdrawal reactions and to collect information on any adverse events that had occurred during this period. For ethical reasons, patients willing to continue receiving study drug after completion of the 6-week treatment period were provided with study medication and maintained on the same medication in blind conditions until the study was completed in the last patient and all the CRFs were collected. Efficacy was assessed by HAMD and CGI at monthly visits. Adverse events were also recorded at monthly intervals and ECG and laboratory values at 3-monthly intervals. The medications were prepared as described for the initial double-blind phase, but in monthly, instead of weekly, units (see Section 3.4.5). Following completion in the last patient of the study and collection of all the CRFs, follow-up was performed under open conditions. The follow-up results will be reported separately in an Addendum to the present report

3.8 GCP Compliance, Data Quality Assurance

The study was initiated before the formal adoption of GCPs by European Regulatory Authorities and in the absence of Company Standard Operating Procedures. However, operating procedures for study monitoring and co-ordination were defined and are described in Attachment A of Appendix 12.1.1.

The study was conducted in accordance with the Declaration of Helsinki, adopted by the 18th World Medical Assembly, Helsinki, June 1964, and amended by the 41st World Medical Assembly, Hong Kong, 1989. A copy of declaration of Helsinki can be found in Enclosure 15 of Appendix 12.1.1. Inter-rater reliability sessions with training purpose on the instrument used for the assessment of change, and particularly on the HAMD, were carried out during the investigators meetings organised by country and/or the monitoring visits by employing 4 videotaped interviews.

During the Study monitoring visits, made at regular intervals, the monitor validated the content of the CRF against source documents, on the basis of the agreed procedures.

Site, trial master file and report audits were carried out by the Company Quality Assurance Unit.

3.9 Statistical Analysis

3.9.1 DETERMINATION OF SAMPLE SIZE

The main evaluation of reboxetine effectiveness was based on the comparison with placebo of the difference between the HAMD score as measured at the last valid assessment and the same score as above as measured at the study entry.

In agreement with this goal the following system of hypotheses was set up:

$$H_0 : \delta_{\text{RBX}} \leq \delta_{\text{PLC}}$$

$$H_a : \delta_{\text{RBX}} > \delta_{\text{PLC}}$$

where δ_{RBX} and δ_{PLC} are the true mean differences of HAMD scores in reboxetine and placebo arm, respectively. Imipramine arm was included in order to ensure the sensitivity of the experimental setting.

In order to take into consideration the multiple comparisons carried out, the overall 0.05 Type I error was halved in the computation of the sample size.

From the Phase II experience [6] and from the literature [7] it seemed reasonable to assume that the treatments groups would have shown a variability (expressed as standard deviation) of 9 points.

Considering of clinical relevance a difference between either reboxetine or imipramine and placebo of at least 4 points, 80 patients in each treatment group were necessary to provide the test with a power ≥ 0.80 if the alternative hypothesis was true with an α level 0.025 for each of the two tests.

The number of required patients was increased to the actual number recruited, in order to take into consideration that drop-outs might have increased variability.

3.9.2 ANALYSES CARRIED OUT

3.9.2.1 Baseline Comparability of Treatments Groups

Baseline characteristics (e.g. age, diagnosis, age at onset, number of previous episodes) which might have influenced the main end-point of the study were summarised considering all the patients entered into the study and subsequently randomised either to reboxetine or to imipramine or to placebo arm.

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3.9.2.2 Efficacy Analyses

Definitions

The following definitions apply to the set of data analysed:

HAMD decrease	The difference between the end of treatment and baseline measurements of HAMD total score. Either the last per-protocol assessment, when the patient regularly completed the study, or the last assessment before dropping out was taken as the end of treatment.
Remission	HAMD total score lower than or equal to 10 (absolute value).
Response	HAMD total score decrease equal to or greater than 50% of the pre-treatment value (Baseline: visit 0). According to this definition and based on the inclusion criterion which required a HAMD total score at entry at least greater than 22, all patients who achieved a remission (as defined above) were included into the broader category of response ($22 \times 0.5 = 11$).
Time to response	Number of days elapsing between the first visit date (Baseline) and the date when first the patient achieved the response (according to the above definition), which was afterwards maintained until the end of the study or earlier termination. This definition excludes patients who achieved occasional response, but were not classified as such at the last observation.
Severe patients	Patients scored 5 to 7 (markedly to extremely ill) on CGI-Severity of Illness scale [10] at entry.
Melancholic patients	On the basis of applicable DSM IV criteria [14]: presence of item 2, i.e. loss of pleasure in all or almost all daily activities in the DSM-III-R classification at entry, and of at least three of the following items in the day 0 HAMD scale: late insomnia (item 6) of maximal severity; agitation (item 9) or retardation (item 6) of at least moderate severity; definite loss of weight (item 16) or loss of appetite (item 12) of maximal severity; diurnal variation with worsening in the morning (item 18); excessive or inappropriate guilt (score 2 or 3 of item 2).

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Methods

The data set analysed included all the patients entered, with the only exception of those patients who did not have at least one post-baseline evaluation.

Efficacy variables, including HAMD and MADRS total score, as well as CGI, were summarised by descriptive statistics (mean, standard deviation -SD-, minimum, maximum, or distribution of frequency of scores) as calculated both at each visit and considering the last valid observation, in the three treatment groups. In particular, in order to describe the time pattern of last valid observation values, one table reports descriptive statistics visit by visit only for those patients who drop the study at that particular time.

The frequency of patients improved, unchanged or deteriorated as for the CGI-Severity of Illness at last assessment compared to baseline was also presented.

The primary end-point for efficacy analysis was HAMD decrease. Treatment mean decreases were analysed by one-way ANOVA [15] and each of the active treatments (reboxetine and imipramine) mean decrease was compared with the one of placebo treatment by one-tailed Dunett's t-test [16]. This test ensures an overall Type I error of 0.05 for the two comparisons carried out. Moreover the 95% C.I. of the difference between the HAMD decrease in the two active treatments was calculated.

Although not strictly necessary to the analysis of differences from baseline, homogeneity of baseline HAMD total scores across treatment groups was tested by ANOVA, in order to assess the comparability of the disease severity within each assignment group. No transformation of the original variable was deemed necessary being the outcome variable the difference between two random variates and as such known to tend to be normally distributed; homogeneity of variances was tested by Bartlett's test [17].

Ninety-five percent confidence intervals (two-tails) of the mean difference of each treatment were computed using in the computation the standard error (SE) obtained by the ANOVA. No baseline characteristics among the one initially tested (i.e. sex and diagnosis, namely first episode *vs* recurrence) were included into the final model analysed, since they didn't increase the variability explained by the model and there was no significant interaction between each of them and the treatment.

The same sets of analyses were carried out on the subset of severe and melancholic patients as defined above.

Complementary to the quantitative analysis of HAMD total score, the qualitative analysis classifying the patients according to the above definition as either responder or failure at last valid assessment was carried out. Independent Chi square tests [18] were applied, in order to compare either reboxetine or imipramine with placebo.

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Document 9550082

No hypothesis was anticipated in the protocol for these comparisons, since this analysis was intended as simply confirmatory of the analysis of the main end-point, i.e. the quantitative evaluation of HAMD. However, a *post-hoc* calculation of the power of the test carried out indicated that a trial of such a size, aiming at identifying a treatment difference as big as 20%, would have had a power greater than 85% in the extreme case of a two tailed test at an α -level 0.025, allowing for protection for multiple comparisons.

The cumulative probability of the onset of response (time to response) was computed adopting the Kaplan-Meier method and pairwise comparisons between each of the active treatments and placebo were carried out by the log-rank test [19].

3.9.2.3 Safety Analyses

Vital signs as measured at each assessment time were summarised by descriptive statistics. Patients with orthostatic hypotension (a decrease ≥ 30 mmHg of systolic blood pressure from lying to standing) were described. Moreover, the frequency of patients showing clinically relevant (20% or more vs baseline) or such a modification accompanied by absolute critical values (≥ 160 or ≤ 100 mmHg for systolic blood pressure; ≥ 100 or ≤ 70 mmHg for diastolic blood pressure; ≥ 100 or ≤ 50 beats/min for heart rate) at each evaluation time were tabulated.

ECG have been summarised in frequency tables, showing normal/abnormal findings at each visit. Changes from baseline (i.e. normal to abnormal and viceversa) have been displayed.

For all the laboratory examinations and within each of the three treatments, the following analyses have been provided:

- frequency and percentage of patients whose values were below, equal or above the normal range at baseline and shifted to values below, within or above the normal range at each visit. Either MacNemar test or Stuart Maxwell test [20] has been applied, in order to test if the distribution across categories at baseline differs from the distribution at each visit.
- continuous values of laboratory tests were standardised according to a method proposed by Chuang-Stein [21] , using as reference values mainly the one reported in Cecil Textbook of Medicine [22] (see Appendix 12.1.8); the Wilcoxon Rank Signed test for paired data [23] was applied, in order to compare the values during treatment with those recorded at baseline.

The usage of statistical tests in this framework aimed mainly at providing screening tools for selecting the relevant changes within each single examination, to this purpose the tests were considered as statistically significant if $p < 0.01$.

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Document 9550082

Moreover, abnormal values of laboratory tests defined as clinically relevant were specially considered and their frequencies at each visit computed. The criteria used to define the observed modifications of laboratory values with respect to baseline as clinically relevant are reported in Appendix 12.1.8.

In the analysis of the adverse events, the attention has been focused on treatment emergent signs and symptoms, i.e. events that were not present at baseline and appeared during treatment or, if present at baseline, became more severe during treatment. The analyses were essentially descriptive and for each treatment group, they were performed in terms of both patients complaining of adverse events and events.

The analyses were performed taking into account the occurrence of at least one sign or symptom, the occurrence of at least one event for each body system or selected aggregation of symptoms (cluster) likely to share the same underlying mechanism or described with synonyms and, in detail, the occurrence of each type of sign or symptom. The events occurred during the study that were grouped in clusters are described in Appendix 12.1.9. When severity of the events was considered, the worst reported degree was selected. In order to explore possible differences, patients were also classified by sex and age.

The cumulative risk of developing the first adverse event, as well as individual adverse event and adverse event clusters (newly emerged in 5% or more of patients in at least one treatment group) was estimated by Kaplan-Meier method. Furthermore, the weekly frequency of patients experiencing adverse events (either because of the onset of new events or because of the persistence of those previously developed) was assessed.

The events have been described by frequency tables according to duration, onset time, symptomatic treatment, relationship to study medication, study drug adjustment, dechallenge/rechallenge after action on study drug and outcome. The duration of any event was computed as the number of days from its onset up to its recovery or, in the absence of recovery date, up to the last reporting date (approximate duration).

3.9.2.4 Changes in the Conduct of the Study or Planned Analysis

No deviation of the main end-point was introduced into the final analysis. In general, analyses carried out were consistent with the ones anticipated in the protocol with a few exceptions:

- a) subset analyses of severe and melancholic patients was introduced.
- b) safety was presented in a more articulated fashion than that anticipated into the protocol.

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Both the deviations were introduced to give a better picture of the product profile and no extra claim is being done on the results obtained.

3.10 Data Management

Data management was carried out in the Biometrics and Data Management Department of Pharmacia, Milan.

CRFs data were entered into a IBM 3090 computer (according to the arrival flow) through data entry masks generated by SAS FSP release 6.06 and 6.07.

Subsequently, data were scrubbed by an electronic procedure set up to this purpose, which generated listings of discrepancies between the actual value entered and predefined algorithms. Computer programs generated to this purpose are archived in Biometrics and Data Management Department. These listings were reviewed by clinical personnel and editing of CRFs were requested at the Investigator site, whenever appropriate.

Corrections were entered iterating the loop until the files were completely cleaned.

ECG tracings were classified and subsequently grouped according to the codes reported in Appendix 12.1.10. Previous and concomitant diseases were coded according to ICD9 dictionary [24]; concomitant drugs according to the Drug Reference List [25]; adverse events according to the WHO-ART dictionary [26]. In the absence of an adequate WHO-ART dictionary code, blurred vision was coded under the preferred term of vision abnormal and urinary hesitancy under the preferred term of micturition disorder. In addition is to be noticed that the dictionary subsumes under the preferred term of suicide: attempt suicide, suicide attempt and suicidal tendency.

Reporting, as well as statistical analyses, were carried out with SAS PROCs (version 6.07), apart from Stuart-Maxwell test and confidence interval calculation. The programs relevant to the latter ones are appended in Appendix 12.1.11. A selection of statistical analyses outputs is shown in Appendix 12.1.12.

4. STUDY PATIENTS

4.1 Disposition of Patients

Randomisation list is given in Appendix 12.1.7.

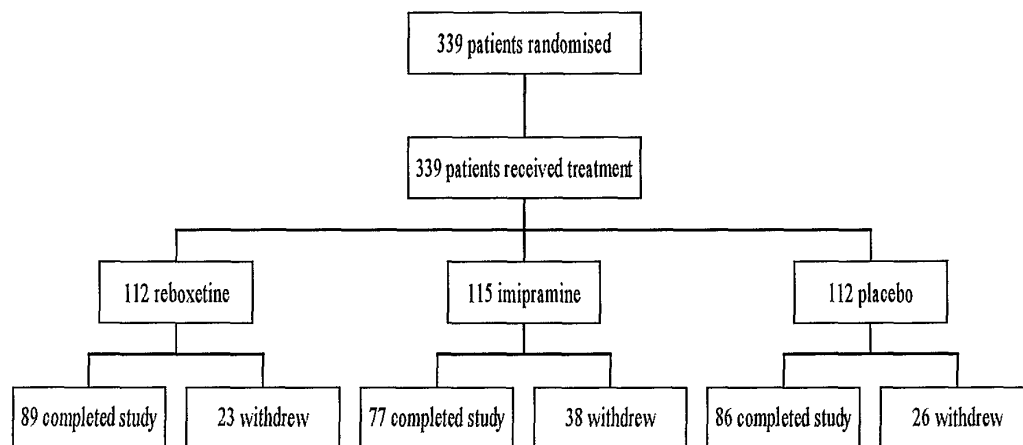
Three hundred and thirty-nine patients (201 females and 138 males) were admitted to the study from January 1991 to October 1992 and randomised to treatment by investigators at 34 centres, as shown in Table 1.

As shown in Table 2, a total of 252 patients (74.3%) completed the study and 87 (25.7%) withdrew; 23 (20.5%) in the reboxetine group, 38 (33.0%) in the imipramine group, and 26 (23.2%) in the placebo group. Frequency and timing of withdrawal are shown by the primary reason for withdrawal in Table 3.

Adverse events or intercurrent illnesses were the main reason for withdrawal in 12, 15 and 8 patients of the reboxetine, imipramine and placebo groups, respectively. The discontinuation for newly emerged adverse events occurred in 11 (9.8%), 15 (13.0%) and 7 (6.3%) on reboxetine, imipramine and placebo respectively. In fact, two patients dropped out the study due to intercurrent medical problems without having a newly emerged adverse event form filled in the CRF: one patient (No 416 from the reboxetine group) dropped out due to the discovery of hypothyroidism which was present before the start of treatment, and a second patient (No 138 from the placebo group) due to bad hepatic function. Adverse events associated with discontinuation in individual cases are discussed in the Adverse Event Section (Section 8.2.3.2). Deterioration was the reported reason for withdrawal in 5, 11 and 11 patients of the reboxetine, imipramine and placebo groups, respectively, i.e. it was given as the reason for withdrawal approximately twice as often by imipramine and placebo group patients compared with reboxetine group patients. Five, eight and six patients were withdrawn due to the non-compliance in the reboxetine, imipramine and placebo group, respectively, while two patients on imipramine and one on placebo were lost to follow up. One patient on imipramine stopped the experimental treatment due to improvement. In the reboxetine group, one patient interrupted the study because of a protocol violation (significant irregularities in drug compliance), and in the imipramine group one patient died (committed suicide) and one discontinued for other reasons (decision of the Principal Investigator at the centre).

The disposition of patients is shown in the following figure and in Table 2.

Disposition of patients



4.2 Protocol Deviations

Compliance with entry criteria

The frequency of non-compliance with inclusion/exclusion criteria of relevance for inferential purpose is given in Table 4. The most frequent reason (4.5%, 10.4% and 5.4% in the reboxetine, imipramine and placebo group patients, respectively) for possible non-compliance with one of the exclusion criteria was related to abnormalities of thyroid function tests, possibly suggestive of an underlying, undiagnosed endocrine disorder. Concomitant medications not allowed according to the protocol during the wash-out period were administered to 5.4% of the reboxetine group patients, 2.6% of the imipramine group patients and 0.9% of the placebo group patients.

Randomisation

Distribution and use of study medication were to be done, as previously mentioned, in blocks of 6 treatments, used in sequence from the smallest to the highest number, according to patient temporal entry into the study. In order to provide a discrepancy log with respect to the randomisation sequence, patients were listed according to their study entry date and the treatment foreseen to be assigned, according to the random sequence of the blocks available at the centre, was matched by a sequential criterion. Mismatching between the foreseen treatment and the treatment actually received was identified as a randomisation error.

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As reported in Table 5, errors in randomisation procedures led to administration of non-randomised treatment to a few patients, at a similar frequency in all three treatment groups. Of the 111 patients randomised to reboxetine, 16 received imipramine and 15 received placebo treatment; of the 114 randomised to imipramine, 19 received reboxetine and 6 received placebo, and of 112 patients randomised to placebo, 12 received reboxetine and 9 received imipramine. For 2 patients (1 on reboxetine and 1 on imipramine) was not possible to identify the treatment which had to be assigned and they were considered out of randomization. All the patients were analysed according to the treatment received.

Assessment intervals

The summary statistics of the efficacy and safety assessment intervals in days from treatment start are shown in Table 6. There were few deviations from scheduled times and these were mainly related to screen and last laboratory tests and ECG evaluations. The deviation rate was similar in the three treatment groups.

Concomitant medications

The frequency of administration of non-protocolled concomitant medications (because of their psychotropic properties) is given by active principle in Table 7, and by class in Table 8. Non-protocolled drugs were administered to only two patients on imipramine (1 long-acting benzodiazepines and 1 antiepileptics) and to five patients on placebo (1 phenothiazines and 4 long-acting benzodiazepines). There were no withdrawals classified as protocol deviation in either of the three groups.

4.3 Demographic Data

Summary statistics of demographic data are given by treatment group in Table 9 (sex, age, weight, height) and Table 10 (race), and summarised below.

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Summary of Demographic Data

		Reboxetine		Imipramine		Placebo	
		n	(%)	n	(%)	n	(%)
Sex	Female	70	62.5	77	67.0	54	48.2
	Male	42	37.5	38	33.0	58	51.8
	Total	112	100	115	100	112	100
Race	Caucasian	111	99.1	114	99.1	108	96.4
	Asian	0	0.0	0	0.0	2	1.8
	Other	1	0.9	1	0.9	2	1.8
	Total	112	100	115	100	112	100
		mean	SD*	mean	SD*	mean	SD*
Age (years)		45.9	12.7	43.5	11.1	43.3	11.7
Height (cm)		166.1	9.3	165.7	8.9	167.8	8.4
Weight (kg)		68.6	15.3	67.4	13.1	69.7	14.1

*SD standard deviation

The majority of patients, in the reboxetine and imipramine groups, were female, but the percentage of females and males was about the same in the placebo group. The vast majority of patients were Caucasian and only 2 patients were Asian. Of the 4 patients with unspecified race, the investigators reported in CRF their nationality (2 patients from Iran, one in both the reboxetine and imipramine groups, and 2 patients, from Madagascar and Sri Lanka respectively, in the placebo group). All treatment groups were well matched for age, height, weight and race.

4.3.1 DIAGNOSIS AND HISTORY OF THE DEPRESSIVE DISORDER

The frequency of the DSM-III-R diagnostic classifications, the summary statistics of the history of the depressive disorder, and the characteristics of the index episode are given by treatment, and sex, in Tables 11 and 12. Recurrent Major Depressive Disorder (DSM-III-R No 296.3) was diagnosed for the majority of patients in each treatment group (67.9% reboxetine, 69.6% imipramine, and 73.2% placebo). A Major Depression First Episode (DSM-III-R No 296.2) was diagnosed in almost all remaining cases, except for 2 patients (1 reboxetine and 1 imipramine) who were diagnosed as Bipolar Disorder, Depressed, unspecified (DSM-III-R No 296.5).

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The age of onset, the median number of previous episodes of depression, the median duration of the last episode and the median duration of the present episode of the patients at entry into the study are shown below.

Previous History of Depression

	Reboxetine			Imipramine			Placebo		
	n	median	range (min-max)	n	median	range (min-max)	n	median	range (min-max)
Age at onset (years)	97	39	13-72	98	37	14-59	99	36	14-59
Number of previous episodes	72	2.0	1-20	76	2.5	1-40	76	2.0	1-11
Duration of the last episode (weeks)	76	12	4-52	76	12	2-156	80	12	1-364
Duration of the present episode (weeks)	112	8	3-16	115	8	3-20	112	8	3-24

The treatment groups were well matched with regard to all the tests characterising the history of mental disorders, as well as for the MMS total scores (Table 12.1).

As shown in Table 12, the onset of the index episode was acute or subacute in the majority of the patients in each treatment group (71.4% of the reboxetine group patients, 85.2% of the imipramine group patients, and 75.9% of the placebo group patients). A precipitating external stress was absent in a similar proportion of patients in each treatment group (39.3%, 40.9%, 39.3% in the reboxetine, imipramine and placebo groups, respectively).

4.3.2 SEVERITY OF DEPRESSION

The severity of the depression, according to the HAMD, MADRS, CGI and RDRS scales, at the various assessment intervals during the study is displayed in terms of summary statistics in Tables 19 to 41 and summarised below at Day 0 for those patients with at least one assessment in addition to baseline. There was no significant difference between the treatment groups at Day 0 with regard to the mean HAMD total scores. Similarly, there were no significant group differences for the initial CGI, RDRS and MADRS scores.

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Severity of Depression at Day 0

	Reboxetine			Imipramine			Placebo		
	n	mean	SD*	n	mean	SD*	n	mean	SD*
HAMD	110	27.5	5.1	111	26.9	4.7	111	27.1	5.3
MADRS	110	16.4	3.9	111	16.7	3.4	111	16.3	3.5
RDRS	109	18.8	7.0	111	18.6	6.2	111	18.0	7.0
		n	(%)		n	(%)		n	(%)
CGI Severity									
Normal		0	0.0		0	0.0		0	0.0
Borderline mentally ill		0	0.0		0	0.0		0	0.0
Mildly ill		1	0.9		2	1.8		4	3.6
Moderately ill		33	29.7		29	26.1		38	34.2
Markedly ill		54	48.6		64	57.7		51	45.9
Severely ill		22	19.8		15	13.5		18	16.2
Extremely ill		1	0.9		1	0.9		0	0.0

*SD standard deviation

On the whole, there were no major imbalances between the three treatment groups in terms of demography, psychiatric medical history and characteristics of the index episode.

4.3.3 PREVIOUS ANTIDEPRESSANT TREATMENTS

Frequency of treatment of previous or index episode with different antidepressant drugs is given by active principle in Table 13. As expected, tricyclic antidepressants were the most frequently prescribed drugs; selective serotonin reuptake inhibitors (with the exception of fluoxetine and fluvoxamine) and monoamine oxidase inhibitors were infrequently mentioned. Active principles are similarly represented in the three treatment groups.

4.3.4 MEDICAL HISTORY

The medical history and medical examination findings at entry to the study are summarised by single disease entity in Table 14, and by affected body system in Table 15. A minority of

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the patients had history or presence of diseases other than the affective disorder at admission. No imbalances among the three treatment groups are apparent.

5. STUDY MEDICATION AND COMPLIANCE

The frequency of administration of different doses of each experimental treatment on each study day is given by treatment in Table 16. The per protocol dose was administered to the vast majority of the patients. On Day 1, 20/112 (17.9%) of the reboxetine group patients, 17/115 (14.8%) of the imipramine group patients and 22/112 (19.6%) of the placebo group patients received half of the protocolled number of daily capsules, because they started their treatment in the afternoon. This resulted in a Day 1 dose of 4 mg of reboxetine, 50 mg of imipramine and 1 capsule of excipients, respectively. Over the next few days a maximum of 3 patients per day in the reboxetine group, 7 patients per day in the imipramine group and 5 patients per day in the placebo group had their number of daily capsules decreased (for the reasons indicated in the individual data listing for the experimental treatment). These were mainly missed intake, lost medication or emergence of signs/symptoms of intolerance.

At the end of the initial 3 weeks of treatment (Table 16.1), 21 patients of the reboxetine group (18.8% of patients treated), 18 of the imipramine group (15.7% of patients treated), and 39 of the placebo group (34.8% of patients treated) had the daily dose increased according to the protocol provisions to a dose corresponding to 10 mg of reboxetine and 200 mg of imipramine (level 2 dose). In the following days, 5 additional patients in the reboxetine group, 3 patients in the imipramine group and 5 patients in the placebo group were changed to level 2 dose. Over the following period, a maximum of 3 patients in both the reboxetine and imipramine groups, and a maximum of 2 patients in the placebo group, had their number of daily capsules decreased (for the reasons indicated in the individual data listing for the experimental treatment). These were mainly missed intake, lost medication or emergence of signs/symptoms of intolerance. During this period, on several treatment days, 3 reboxetine patients, 2 imipramine patients and 3 placebo patients mistakenly took both level 1 and 2 doses, corresponding to 18 mg/day of reboxetine, 350 mg/day of imipramine and 4 capsules per day of placebo (Table 16).

Comparison of the daily dose administered (as reported in the compliance section of the CRF) with the expected dose (as indicated in the Experimental Treatment Section of the CRF) allowed calculation of the compliance with the treatment regimen. Full compliance was defined where there was full agreement between the dose prescribed (the per protocol dose, or a lower dose, mainly in case of adverse events) and the dose reported to have been taken. The total compliance over the treatment period was calculated for each patient and the patients were classified accordingly (Table 17). One hundred per cent compliance was reported in 68.8% of the reboxetine group patients, 70.4% of the imipramine group patients, and 75.0% of the placebo group patients. Only in a few cases the reported

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compliance was lower than 80% (3 imipramine group patients and 2 placebo group patients) or between 80% and 89% (5 reboxetine group patients, 2 imipramine group patients and 1 placebo group patient). The remaining patients reported a total compliance between 90% to 99% (26.8% of reboxetine, 25.2% of imipramine and 22.4% of placebo patients).

6. CONCOMITANT MEDICATIONS

The absolute and per cent frequencies during the treatment period, of those patients who received concomitant medications, either as a continuation of baseline therapy or as a newly introduced medication for treatment emergent events, is shown in Table 18. In addition to those non-protocolled psychotropic medications discussed previously in Section 4.2, other drugs were occasionally administered, generally following the emergence of adverse events, at similar frequency in the three treatment groups.

7. EFFICACY RESULTS

Every randomised patient with at least one assessment in addition to baseline was considered as evaluable for efficacy analysis.

Eighty-nine out of the 110 evaluable patients on reboxetine, 77 out of the 111 evaluable patients on imipramine and 86 out of the 111 evaluable patients on placebo completed the study, while 89 patients on reboxetine, 79 on imipramine and 87 on placebo had the last assessment at the Day 42 visit, in spite of the fact that three of them (2 in the imipramine and 1 in the placebo group) withdrew from the study during the last week of the treatment (in comparison with the Table 2 and related figure at page 53).

7.1 Hamilton Depression Rating Scale

Summary statistics of HAMD assessment at each visit in the observed cases are shown in Table 19 (total scores), Table 20 (factors) and Table 21 (individual items). Summary statistics of the last assessment are given in Table 22 (total scores), Table 23 (factors) and Table 24 (individual items). The mean HAMD total score was reduced from 27.5 at Day 0 to 14.0 at last assessment (mean decrease 13.5, 95% C.I.: 11.6 ÷ 15.4), in the 110 patients randomised to reboxetine who had at least one assessment in addition to baseline (2 patients had only baseline data), and to 11.3 at Day 42 in the 89 patients who completed the study. In the 111 patients randomised to imipramine with at least one assessment in addition to baseline (4 patients had only baseline data), the mean HAMD total score was reduced from 26.9 at Day 0 to 13.2 at last assessment (mean decrease 13.8, 95% C.I.: 11.9 ÷ 15.7), and to 9.4 at Day 42 in the 79 patients still on treatment. Mean HAMD total scores in the 111 patients randomised to placebo were reduced from 27.1 at Day 0 to 15.8 at last assessment (mean decrease 11.3, 95% C.I.: 9.4 ÷ 13.2), and to 13.1 at Day 42 in the 87 patients still on

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treatment. In order to give a better insight of the estimated mean decrease, the two-tailed 95% confidence interval for each arm is shown in Figure 1.

The between treatment difference in HAMD total score at last assessment (study end-point) is not statistically significant ($p > 0.025$, one-tailed test) for both the reboxetine vs placebo and the imipramine vs placebo comparisons.

The pattern of improvement of HAMD factors was similar in the reboxetine-treated and imipramine-treated patients. At the last assessment, the most clear placebo-active treatment differences were seen in: Factor V (Retardation), the most severely affected at baseline, (median difference vs Day 0 of 1.00 [reboxetine group] and 1.00 [imipramine group] and vs 0.75 [placebo group]); Factor I (Anxiety-Somatisation) (median difference vs Day 0 of 0.67 [reboxetine group] and 0.67 [imipramine group] vs 0.50 [placebo group]); and Factor III (Cognitive Disturbances) (median difference vs Day 0 of 0.50 [reboxetine group] and 0.50 [imipramine group] vs 0.33 [placebo group]).

Absolute and per cent frequency of patients who achieved response or remission is shown (with 95% confidence intervals) by treatment group over time in Table 25 and at last assessment in Table 26. The percentage of responders at each visit is higher in the reboxetine group (20.0%) in comparison with the placebo group (9.7%) from Day 14 onwards, and in the imipramine group is higher in comparison with the placebo group from Day 7 onwards (7.2% vs 4.5%, respectively). The percentage of responders is somewhat higher in the imipramine group compared to reboxetine group in the intermediate assessments up to Day 42, except for Day 35 (64.6% vs 65.6%, respectively). In comparison with placebo, the percentage of patients in remission was higher in the reboxetine group from Day 14 onwards (11.4% vs 4.9%) and in the imipramine group from Day 7 onwards (7.2% vs 0.9%). The percentage of remissions was higher in the imipramine group compared with the reboxetine group in the intermediate assessments up to Day 42, except for Day 14 (8.9% vs 11.4%, respectively).

At last assessment (Table 26) 59.1% of the 110 reboxetine-treated patients, 62.2% of the 111 imipramine-treated patients and 52.3% of the 111 placebo-treated patients were classified as responders, while 42.7%, 50.5% and 36.0%, respectively, were seen to be in remission. The between treatment difference in the proportion of remissions and responders both for imipramine and reboxetine compared with placebo did not reach the statistical significance ($p > 0.025$).

The cumulative probability of response (confirmed at all available subsequent assessments) is plotted according to the Kaplan-Meier method in Figure 2. Patients on imipramine had a cumulative probability of response significantly higher ($p = 0.0055$) from patients on placebo, while patients on reboxetine had a probability of response whose difference from placebo didn't reach statistical significance ($p = 0.081$). The time to response appears to be

somewhat quicker on imipramine than on reboxetine: the between treatment difference was, however, far from significant.

Additional analyses were carried out on the sub-populations of patients classified as markedly to extremely ill at admission (according to the CGI-Severity of Illness scale) and on those characterised as melancholic (DSM IV criteria) at admission (possible for 295 of the 339 patients admitted (Appendix 12.1.12), in view of the missing information on time frame of diurnal variation, scored as present at the relevant HAMD item).

The mean decrease at last assessment of the HAMD total score in patients classified as markedly to extremely ill at admission in the three treatment groups (77 reboxetine, 80 imipramine and 69 placebo) is shown, together with the 95% confidence interval, in Figure 3. With respect to the total population (Figure 1), the improvement on both active treatments was maximal and on placebo it was minimal. The mean decrease in the two active treatments was very similar, the mean difference between imipramine and reboxetine being of 0.12 points (95% C.I.: -3.2 ÷ 3.4). However the difference between active treatments compared to placebo was statistically significant ($p < 0.025$) only for imipramine.

The mean decrease at last assessment of the HAMD total score in those patients which could be classified as melancholic at admission in the three treatment groups (melancholic/non-melancholic: 51/46 reboxetine, 44/53 imipramine, 41/60 placebo (Appendix 12.1.12)), is shown, together with the 95% confidence interval, in Figure 4. The difference between active treatments and placebo was statistically significant for reboxetine, but not for imipramine. The mean difference between active treatments was in favour of reboxetine, with a value of 3.9 points (95% C.I.: -0.5 ÷ 8.3).

7.2 Clinical Global Impression

7.2.1 SEVERITY OF ILLNESS

The distribution of the CGI severity scores at each visit in the observed cases is presented by treatment group in Table 27, while the distribution of the scores at the last assessment during the study are provided in Table 28. The distribution pattern is clearly different in the three treatment groups, the most important difference being seen in the proportion of normal or borderline cases in the two active treatment groups compared to placebo. This corresponds, at last assessment, to 43.6% of the cases on reboxetine, 44.1% of the cases on imipramine and 29.7% of the cases on placebo. Only two patients (1 on imipramine and 1 on placebo group) were extremely ill at last assessment.

A shift table of the last record vs Day 0 (Table 29) showed that the CGI severity of illness had decreased in 77.3% and 77.5% of the reboxetine- and imipramine-treated patients, respectively, compared with 65.8% of the placebo-treated patients, increased in 5.5% and

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4.5% of the reboxetine- and imipramine-treated patients, respectively, compared with 8.1% of the placebo-treated patients, and had remained the same in the 17.3% and 18.0% of reboxetine- and imipramine-treated patients compared with 26.1% of the placebo-treated patients.

7.2.2 GLOBAL IMPROVEMENT

The distribution of Global Improvement scores in CGI at each visit is shown by treatment group in Table 30. The distribution of last assessment scores is shown in Table 31.

The clearest difference between treatments is related to the percentage of patients who were 'very much improved' at last assessment; this was higher in the reboxetine group (29.1%) and the imipramine group (28.8%) compared with the placebo group (17.1%). The same difference was observed at Day 42 in the patients who completed the study: 34.8% of the 89 reboxetine patients and 39.2% of the 79 imipramine patients compared with 20.7% of the 87 placebo patients. In addition, the percentage of patients at last assessment with 'no change' was higher in the placebo group (17.1%) than in the reboxetine group (9.1%) and imipramine group (10.8%).

7.2.3 EFFICACY INDEX

The CGI efficacy index, which was assessed in order to relate therapeutic efficacy and tolerability, is shown by treatment group at each visit in Table 32. The distribution of last assessment values is shown in Table 33. At last assessment side-effects were judged to outweigh efficacy in 15.3% of the reboxetine patient group, 16.2% of the imipramine patient group and 13.5% of the placebo patient group. The most relevant placebo-active treatment group differences are seen either in the proportion of cases where no advantage in terms of efficacy vs side-effects was identified (index = 1), i.e. 21.6% of the placebo-treated cases compared with 13.5% of the reboxetine-treated and 13.5% of the imipramine-treated cases, and in the proportion of cases where efficacy outweighed side-effects (index = 4), i.e. 22.5% of the placebo-treated cases, compared with 28.8% of the reboxetine-treated cases and only 14.4% of the imipramine-treated cases. A clear benefit from therapy (EI \geq 2) was observed in approximately 62.2% of reboxetine patients compared with 59.5% of both imipramine and placebo patients.

7.3 Montgomery and Asberg Depression Rating Scale

Summary statistics of MADRS assessment at each visit in the observed cases are shown in Table 34 (total scores) and Table 35 (individual items). Summary statistics of the last assessment are given in Table 36 (total scores) and Table 37 (individual items).

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Document 9550082

The mean total MADRS score was reduced from 16.4 at Day 0 to 8.4 (mean difference vs Day 0 of 7.9) at last assessment in the 110 reboxetine group patients with at least one assessment in addition to baseline, and to 6.6 at Day 42 in the 89 reboxetine patients who completed the study. In patients randomised to imipramine, values changed from 16.7 at Day 0 to 8.2 (mean difference vs Day 0 of 8.6) at last assessment (111 patients), and to 5.8 at Day 42 (79 assessed patients). The corresponding reductions in placebo group patients were from 16.3 at Day 0 to 9.8 (mean difference vs Day 0 of 6.5) at last assessment (111 patients) and to 7.7 at Day 42 (87 assessed patients).

7.4 Relational Depression Rating Scale

Summary statistics of RDRS assessment at each visit in the observed cases are shown in Table 38 (total scores) and Table 39 (individual items). Summary statistics of the last assessment are given in Table 40 (total scores) and Table 41 (individual items).

The mean total RDRS score was reduced from 18.8 at Day 0 to 9.6 (mean difference vs Day 0 of 9.2) at last assessment in the 109 reboxetine patients with at least one assessment in addition to baseline, and to 7.6 at Day 42 in the 88 reboxetine patients who completed the study. In patients randomised to imipramine, values changed from 18.6 at Day 0 to 9.1 (mean difference vs Day 0 of 9.5) at last assessment (111 patients), and to 6.5 at Day 42 (79 assessed patients). The corresponding reductions in placebo group patients were from 18.0 at Day 0 to 11.1 (mean difference vs Day 0 of 6.9) at last assessment (111 patients) and to 9.4 at Day 42 (86 assessed patients).

7.5 Efficacy Conclusion

In the 110 patients randomised to reboxetine who had at least one assessment in addition to baseline, the mean HAMD total score was reduced from 27.5 at Day 0 to 14.0 at last assessment, and to 11.3 at Day 42 in the 89 patients assessed at Day 42. In the 111 patients randomised to imipramine with at least one assessment in addition to baseline, the mean HAMD total score was reduced from 26.9 at Day 0 to 13.2 at last assessment, and to 9.4 at Day 42 (79 patients). Mean HAMD total score in the 111 patients randomised to placebo was reduced from 27.1 at Day 0 to 15.8 at last assessment, and to 13.1 at Day 42 (87 patients). The results of the planned analysis of the study end-point indicate slightly higher improvement on both reboxetine and imipramine, compared to placebo, though the differences do not reach statistical significance ($p > 0.025$, one-tailed test).

At last assessment, 59.1% of the reboxetine-treated patients, 62.2% of the imipramine-treated patients and 52.3% of the placebo-treated patients were classified as responders, while 42.7%, 50.5% and 36.0%, respectively, were seen to be in remission. The between treatment difference in the proportion of remissions and responders both for imipramine and reboxetine compared with placebo did not reach the statistical significance ($p > 0.025$).

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Document 9550082

Patients on imipramine had a rate of response (Kaplan-Meier method) significantly higher ($p = 0.0055$) than patients on placebo, while patients on reboxetine had a rate of response whose difference from placebo didn't reach significance ($p = 0.081$).

Additional analyses were carried out in the sub-populations of severe (CGI- Severity of Illness: marked to extreme severity at the admission) and melancholic (DSM IV criteria) patients. In severe patients, with respect to the total population, the improvement on both active treatments was maximal and on placebo it was minimal. The mean decrease in the two active treatments was very similar, the mean difference between imipramine and reboxetine being of 0.12 points (95% C.I.: $-3.2 \div 3.4$). However, the difference between active treatments compared to placebo was statistically significant ($p < 0.025$) only for imipramine. In melancholic patients the difference between placebo and active treatments was significantly superior for reboxetine, but not for imipramine. The mean difference between active treatments was in favour of reboxetine with a value of 3.9 points (95% C.I.: $-0.5 \div 8.3$).

The CGI severity of illness had decreased in 77.3% and 77.5% of the reboxetine and imipramine patients, respectively, compared with 65.8% of the placebo patients, increased in 5.5% and 4.5% of the reboxetine and imipramine patients, respectively, compared with 8.1% of the placebo patients, and had remained the same in the 17.3% and 18.1% of reboxetine and imipramine patients, respectively, compared with 26.1% of the placebo patients.

The clearest difference between treatments is related to the percentage of patients who were 'very much improved' at last assessment. This was higher in the reboxetine group (29.1%) and the imipramine group (28.8%) compared with the placebo group (17.1%). In addition, the percentage of patients with 'no change' was higher in the placebo group (17.1%) than in the reboxetine group (9.1%) and the imipramine group (10.8%).

At last assessment, side-effects were judged to outweigh efficacy in 15.3% of the reboxetine patients, 16.2% of the imipramine patients and 13.5% of the placebo patients. The most relevant placebo-active treatment group differences in the Efficacy Index are seen in the proportion of cases where no advantage in terms of efficacy vs side-effects was identified (index = 1) (21.6% of the placebo patients vs 13.5% of the reboxetine patients and 13.5% of the imipramine patients), and in the proportion of cases where efficacy outweighed side-effects (index = 4) (22.5% of the placebo patients vs 28.8% of the reboxetine patients and only 14.4% of the imipramine patients). A clear benefit from therapy ($EI \geq 2$) was observed in approximately 62.2% of reboxetine patients compared with 59.5% of both imipramine and placebo patients.

The mean total MADRS score was reduced from 16.4 at Day 0 to 8.4 (mean difference vs Day 0 of 7.9) at last assessment in the 110 reboxetine group patients with at least one

Pharmacia

Document 9550082

assessment in addition to baseline, and to 6.6 at Day 42 in the 89 reboxetine patients who completed the study. In patients randomised to imipramine, values changed from 16.7 at Day 0 to 8.2 (mean difference vs Day 0 of 8.6) at last assessment (111 patients), and to 5.8 at Day 42 (79 assessed patients). The corresponding reductions in placebo group patients were from 16.3 at Day 0 to 9.8 (mean difference vs Day 0 of 6.5) at last assessment (111 patients) and to 7.7 at Day 42 (87 assessed patients).

8. SAFETY RESULTS

8.1 Safety Population and Extent of Exposure

8.1.1 NUMBER OF PATIENTS IN SAFETY ANALYSIS

All the patients who received study treatment were included in the safety analysis, i.e. 112 reboxetine patients, 115 imipramine patients and 112 placebo patients.

8.1.2 TOTAL DRUG EXPOSURE

As shown in Table 16, of the 112, 115 and 112 patients exposed to reboxetine, imipramine and placebo, 96, 88 and 96, respectively, were treated at least for 3 weeks, while 89, 77 and 86 were treated at least for 6 weeks.

8.2 Adverse Events

8.2.1 ANALYSIS OF ADVERSE EVENTS

The number of patients with adverse events and the number of adverse events during the study are grouped by sex in Table 42, by age classes in Table 43 and by DSM III-R diagnosis in Table 44; 63.4% of the reboxetine patients, 70.4% of the imipramine patients and 51.8% of the placebo patients exposed to treatment had at least one, and an average of 3, 4 and 2 adverse events, respectively. Females and males suffered from adverse events to a similar extent on reboxetine (62.9% vs 64.3%), on imipramine (70.1% vs 71.1%) and on placebo (53.7% vs 50.0%). Patients aged over 45 years old had adverse events less frequently than those who were 18 to 30 years or 31 to 45 years old on reboxetine (56.1%, 71.4%, 70.7%, respectively) and on placebo (46.8%, 53.3%, 56.0%). On imipramine, the pattern of adverse events was similar in the three age groups (70.4%, 70.6%, 70.5%, respectively).

Patients with no history of previous depressive illness, diagnosed as Major Depressive Episodes (296.2) complained of adverse events less frequently than recurrent cases (296.3) on reboxetine (57.1% vs 67.1%) and placebo (40.0% vs 56.1%) but not on imipramine (70.6% vs 70.0%).

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Document 9550082

8.2.1.1 Absolute and Per Cent Frequency

The absolute and per cent frequency of patients suffering from adverse events is grouped by event and sex in Tables 45 (all events) and 47 (grouped by body system, with relevant events grouped in clusters) and by body system and sex in Table 46. Among the most frequently reported adverse events ($\geq 5\%$ of exposed patients in at least one group) more frequently reported on reboxetine than on placebo were dry mouth (25.0% vs 12.5%), constipation (15.2% vs 5.4%), increased sweating (12.5% vs 2.7%), headache/migraine (13.4% vs 8.0%), vertigo (4.5% vs 0%), insomnia (10.7% vs 3.6%), hypotension and related symptoms (8.9% vs 5.4%), blurred vision (5.4% vs 2.7%) and urinary hesitancy/retention (5.4% vs 1.8%).

More frequently reported on imipramine than on placebo were dry mouth (42.6% vs 12.5%), constipation (15.7% vs 5.4%), increased sweating (19.1% vs 2.7%), nausea and related symptoms (14.8% vs 8.9%), tremor (17.4% vs 4.5%), vertigo (6.1% vs 0%), paraesthesia (5.2% vs 1.8%), insomnia (7.0% vs 3.6%), hypotension and related symptoms (17.4% vs 5.4%) and blurred vision (7.8% vs 2.7%).

The most relevant between-gender differences were noticed in all treatment groups and were related to the frequency of dry mouth, constipation, increased sweating, and nausea, complained of mainly by female patients (27.1%, 45.5%, 18.5% dry mouth; 17.1%, 18.2%, 9.3% constipation; 15.7%, 20.8%, 3.7% increased sweating; 10%, 16.9%, 16.7% nausea and related symptoms) on reboxetine, imipramine and placebo, respectively. The corresponding figures for male patients were 21.4%, 36.8%, 6.9% dry mouth; 11.9%, 10.5%, 1.7% constipation; 7.1%, 15.8%, 1.7% increased sweating; 7.1%, 10.5%, 1.7% nausea and related symptoms, on reboxetine, imipramine and placebo, respectively. Tremor was complained of by more female than male patients (20.8% vs 10.5%) on imipramine, but not on placebo (3.7% of female patients vs 5.2% of male patients) and on reboxetine (5.7% vs 4.8% of female and male patients, respectively). Conversely, urinary hesitancy/retention was complained of by more male than female patients on reboxetine (14.3% vs 0%, respectively), but not by patients on imipramine and placebo (0% and 1.7% vs 1.3% and 1.9% of male and female patients, respectively).

Disorders more frequently complained of by reboxetine and imipramine patients than by placebo patients were disorders of the autonomic nervous system (35.7% and 48.7% vs 15.2%, respectively), gastrointestinal (GI) system disorders (23.2% and 31.3% vs 16.1%, respectively), central and peripheral nervous system disorders (24.1% and 31.3% vs 14.3%, respectively), cardiovascular disorders (14.3% and 24.3% vs 8.9%, respectively). Urinary system disorders were complained of by more reboxetine patients (10.7%) than by imipramine (1.7%) and placebo patients (3.6%).

Pharmacia

Document 9550082

8.2.1.2 Occurrence

The occurrence of adverse events is grouped by week of onset and event or body system in Tables 48, 49 and 50, respectively. The majority of events on reboxetine, imipramine and placebo emerged initially during treatment, within the first week (autonomic NS disorders, 55.6%, 60.8%, 55.6%, GI disorders, 44.4%, 36.0%, 38.7%, respectively; psychiatric disorders, 42.9%, 66.7%, 38.7%; central and peripheral NS disorders, 61.8%, 42.9%, 45.0%; cardiovascular disorders, 38.1%, 43.6%, 20.0%).

8.2.1.3 Overall Risk

The cumulative risk of developing the first adverse event, as well as adverse event clusters or individual events reported in at least 5% of exposed patients in at least one treatment group is described according to the Kaplan-Meier method and analysed by the log-rank test in Figures 5 to 20. As shown in Figure 5, the risk of developing at least one adverse event is significantly higher in the imipramine group compared to placebo ($p = 0.001$) and approaches significance in the reboxetine group ($p = 0.051$). As for individual events or clusters, the cumulative risk is significantly higher on reboxetine than on placebo for insomnia ($p = 0.041$), increased sweating ($p = 0.006$), dry mouth ($p = 0.017$), vertigo ($p = 0.024$) and constipation ($p = 0.016$). Similarly, the cumulative risk is significantly higher on imipramine than on placebo for dry mouth ($p = 0.0001$), constipation ($p = 0.007$), increased sweating ($p = 0.0001$), vertigo ($p = 0.008$), hypotension and related symptoms ($p = 0.003$), blurred vision ($p = 0.042$) and tremor ($p = 0.001$).

The log-rank tests on the direct comparison between reboxetine and imipramine in terms of increased risk of adverse events indicate significant differences in favour of reboxetine for dry mouth ($p = 0.003$), hypotension and related symptoms ($p = 0.041$) and tremor ($p = 0.003$). A slighter difference in favour of reboxetine, but not a significant one, was also noticed for nausea and related symptoms, somnolence and increased sweating, while the difference was in favour of imipramine, but not significantly so, for headache/migraine and urinary hesitancy/retention.

8.2.1.4 Dose-relationship

The absolute frequency of adverse events is grouped by maximal severity and by dose taken on the onset day and in the three preceding days in Table 51. For none of the events and treatments there is any indication of increased frequency or severity in patients (see Table 16) switched according to the protocol to the higher dose level, corresponding to 10 mg/day for reboxetine and to 200 mg/day for imipramine.

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Document 9550082

8.2.1.5 Maximal Severity

The maximal severity of adverse events is grouped by sex age and DSM III-R classification in Table 52 and by event or body system in Tables 53 and 54, respectively. Events were most frequently moderate on imipramine, placebo and reboxetine (50.6%, 51.7% and 39.4%, respectively), while severe events were being reported by 32.4%, 30.9% and 19.0% of reboxetine, imipramine and placebo patients. For two patients (one in the imipramine group died committing suicide and one in the placebo group had a rhinitis) the investigator did not fill in the severity of the event. The major between-gender differences were in the imipramine and reboxetine groups. In the reboxetine group, the events of mild severity were more frequent in male than in female patients (40.7% vs 20.5%), while the events of moderate severity were more frequent in female than in male patients (47.7% vs 25.9%). In the imipramine group, the events of mild severity were more frequent in male than in female patients (33.3% vs 9.3%), while the severe events were more frequent in female than in male patients (38.9% vs 14.8%). Moderateness characterised the severity of events for the majority of the affected body systems: 47.5%, 57.1%, 52.9% of the patients on reboxetine, imipramine and placebo, respectively, for autonomic NS disorders, 65.4%, 55.6%, 66.7% for GI disorders and 48.1%, 61.1%, 62.5% for central and peripheral NS disorders.

8.2.1.6 Duration

Summary statistics of the duration of adverse events are described in Table 55. The median duration was 10 days for reboxetine, 13 days for imipramine and 8 days for placebo. Among the most frequent events, the median duration was higher in both active treatment groups than in placebo group for dry mouth (26 days, 20 days, 15 days on reboxetine, imipramine and placebo, respectively) and tremor (11 days, 20 days, 3 days on reboxetine, imipramine and placebo, respectively); the median duration was similar in the reboxetine and imipramine groups, but lower than that in the placebo group for increased sweating (15 days, 14 days and 35 days, respectively). For constipation, the median duration was lower on reboxetine than on imipramine and placebo (13 days, 23 days, 20 days, respectively), while the median duration for nausea on reboxetine was higher than on both imipramine and placebo (18 days, 6 days, 6 days, respectively).

8.2.1.7 Symptomatic Treatment

As shown in Table 56, 19.0%, 10.4%, and 16.3% of the events on reboxetine, imipramine and placebo, respectively, required symptomatic treatment in 33.8%, 27.2% and 25.9% of the affected patients. Headache and insomnia were the most frequent events leading to symptomatic treatment.

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Document 9550082

8.2.1.8 Modification of Study Medication and Patient Outcome

As shown in Table 57, no change in study medication was required for 85.8%, 81.6% and 88.7% of the events, for patients on reboxetine, imipramine and placebo, respectively, while the daily dose was reduced in 1.9%, 2.1% and 0% of the occurrences, respectively, or the treatment temporarily interrupted in 0%, 1.7% and 1.4%. According to the Adverse Event outcome reported by the investigators, 9.5%, 10.4% and 8.5% of the cases in the reboxetine, imipramine and placebo groups, respectively caused or contributed to treatment withdrawal. This was most frequently seen for increased sweating, nausea and related symptoms and hypotension and related symptoms in the imipramine group, hypotension and related symptoms and anxiety/agitation/nervousness in the reboxetine group and anxiety/agitation/nervousness in the cases from the placebo group. Suicide attempts (one successful) caused withdrawal in 2 cases in the imipramine group and 2 cases in the placebo group. Suicidal ideas caused withdrawal in 1 case in each of the imipramine and the reboxetine groups (the latter classified as discontinuation due to deterioration). The individual cases of patients withdrawn due to adverse events are described in Section 8.2.3.2.

As shown in Table 58, of the 24, 41 and 14 events requiring modification of the study medication in the reboxetine, imipramine and placebo groups, the majority in the reboxetine and imipramine groups (50.0%, 43.9%, respectively) disappeared following the modification of the regimen, while the majority in the placebo group did not (78.6%). The patient outcome (grouped by event and action taken on study medication in Table 59) corresponds to full recovery in 29.2%, 36.6% and 64.3% (7, 15 and 9 events, respectively) of the cases in the reboxetine, imipramine and placebo groups following modification of the treatment regimen. The event was still present at last assessment in 70.8%, 61.0% and 28.6% (17, 25 and 4 events, respectively) of the cases in reboxetine, imipramine and placebo groups, respectively; in 1 case on placebo, the patient had incompletely recovered (recovered with sequelae). In the cases of unchanged study medication, the event was still present at last assessment in 37.4%, 46.6% and 33.9% while was fully recovered in 55.6%, 47.0% and 63.0% of the reboxetine, imipramine and placebo groups, respectively. One patient died in the imipramine group.

8.2.1.9 Prevalence

The prevalence of adverse events is grouped by week of treatment and event, event cluster or body system in Tables 60, 61 and 62. Among the most frequent events, in keeping with the selection of the most tolerant population over the treatment period, the proportion of affected patients tended to decrease during treatment, particularly during the last two weeks, in all treatment groups, with the exception of dry mouth, constipation, urinary

Pharmacia

Document 9550082

hesitancy and dizziness and related disorders in the reboxetine group and of dry mouth, constipation, tremor and blurred vision in the imipramine group.

The overall prevalence of adverse events in the three treatment groups is shown in Figure 21. The proportion of patients affected by at least one adverse event during the different weeks of treatment was higher on both imipramine and reboxetine than on placebo during the whole treatment period. In addition, the proportion of patients was always slightly higher on imipramine than reboxetine, particularly during the fourth and the sixth week.

8.2.1.10 Relationship Between Adverse Events and Study Medication

The relationship between adverse events and study medication, as judged by the investigators on the basis of Karch and Lasagna modified criteria (Enclosure 13 of Appendix 12.1.1) is described in Table 63. The majority of events on reboxetine, imipramine and placebo (48.8%, 53.1%, 36.9%, respectively) were judged possibly related, while 11.4%, 22.2% and 15.6%, respectively, were judged probably related and 2.4%, 2.1% and 4.3%, respectively, were judged definitely related. Among the most frequent events, the maximal frequency of definite/probable relationship was present for dry mouth (27.6%, 35.9%, 40.0%) and increased sweating (26.7%, 38.5%, 66.7%) for reboxetine, imipramine and placebo, respectively.

8.2.2 ADVERSE EVENT SUMMARY

Of the 112 reboxetine patients, 115 imipramine patients and 112 placebo patients who received study medication, 71 (63.4%), 81 (70.4%), and 58 (51.8%) patients reported a total of 211, 288, 141 adverse events, respectively (3, 4, 2 per patient) (Table 42). The cumulative risk of occurrence of adverse events was significantly higher in the imipramine group compared to the placebo group ($p = 0.001$) and approached significance in the reboxetine group ($p = 0.051$), while the risk of developing at least one adverse event was similar in the reboxetine and the imipramine groups (Figure 5). The prevalence of adverse events during the study indicated a higher proportion of patients with adverse events in both imipramine and reboxetine groups than in the placebo group during the whole treatment period. In addition the proportion was always slightly higher on imipramine than on reboxetine, particularly during the fourth and the sixth week (Figure 21).

8.2.2.1 Severity of Adverse Events

The maximum severity of adverse events is presented in Tables 52-54 and summarised as follows:

Pharmacia

Document 9550082

Severity of Adverse Events

No. of patients								
Reboxetine			Imipramine			Placebo		
Mild	Moderate	Severe	Mild	Moderate	Severe	Mild	Moderate	Severe
20	28	23	14	41	25	16	30	11

For two patients (one in the imipramine group died committing suicide and one in the placebo group had a rhinitis) the investigator did not fill in the severity of the event.

Adverse events were more frequently moderate or severe in the reboxetine and imipramine treatment groups, and more frequently mild or moderate in the placebo treatment group.

8.2.2.2 Age- and Gender-Related Effects

Females and males suffered from adverse events to a similar extent on reboxetine (62.9% vs 64.3%), on imipramine (70.1% vs 71.1%) and on placebo (53.7% vs 50.0%) (Table 42). Patients aged over 45 years old had adverse events less frequently than those who were 18 to 30 years or 31 to 45 years old on reboxetine (56.1%, 71.4%, 70.7%, respectively) and on placebo (46.8%, 53.3%, 56.0%). On imipramine, the pattern of adverse events was similar in the three age categories (70.4%, 70.6%, 70.5%) (Table 43). The most relevant between-gender differences were related to the frequency of dry mouth, constipation, increased sweating, and nausea, complained of mainly by female patients (27.1%, 45.5%, 18.5% dry mouth; 17.1%, 18.2%, 9.3% constipation; 15.7%, 20.8%, 3.7% increased sweating; 10.0%, 16.9%, 16.7% nausea and related symptoms) on reboxetine, imipramine and placebo, respectively. The corresponding figures for male patients were 21.4%, 36.8%, 6.9% dry mouth; 11.9%, 10.5%, 1.7% constipation; 7.1%, 15.8%, 1.7% increased sweating; 7.1%, 10.5%, 1.7% nausea and related symptoms on reboxetine, imipramine and placebo, respectively. Tremor was complained of by more female than male patients (20.8% vs 10.5%) on imipramine but not on placebo (3.7% of female patients vs 5.2% of male patients) and on reboxetine (5.7% vs 4.8% of female and male patients, respectively). Conversely, urinary hesitancy/retention was complained of by more male than female patients on reboxetine (14.3% vs 0%, respectively), but not by patients on imipramine and placebo (0% and 1.7% vs 1.3% and 1.9% of male and female patients, respectively) (Table 46).

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Pharmacia

Document 9550082

8.2.2.3 Frequently Reported Adverse Events

Adverse events which occurred in 5% or more of the patients in at least one treatment group are presented by body system in the following table:

Adverse Events Occurring in 5% or More of Patients in at Least One Group

Body system	Adverse event	Reboxetine (n=112)		Imipramine (n=115)		Placebo (n=112)	
		No. of patients with event	% of patients exposed	No. of patients with event	% of patients exposed	No. of patients with event	% of patients exposed
Autonomic NS disorders	Dry mouth	28	25	49	43	14	13
	Increased sweating	14	13	22	19	3	3
GI disorders	Constipation	17	15	18	16	6	5
	Nausea and related symptoms	10	9	17	15	10	9
Central and peripheral NS disorders	Headache / migraine	15	13	9	8	9	8
	Tremor	6	5	20	17	5	5
	Vertigo	5	5	7	6	0	
	Paraesthesia	2	2	6	5	2	2
Psychiatric disorders	Agitation / anxiety / nervousness	11	10	5	4	10	9
	Insomnia	12	11	8	7	4	4
	Somnolence	1	1	6	5	9	8

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Pharmacia

Document 9550082

Adverse Events Occurring in 5% or More of Patients Continued

Body system	Adverse event	Reboxetine (n=112)		Imipramine (n=115)		Placebo (n=112)	
		No. of patients with event	% of patients exposed	No. of patients with event	% of patients exposed	No. of patients with event	% of patients exposed
General cardiovascular disorders	Hypotension and related symptoms	10	9	20	17	6	5
Vision disorders	Abnormal vision / accommodation abnormal	6	5	10	9	3	3
Body as a whole - general disorders	Asthenia / fatigue	4	4	6	5	4	4
Urinary system disorders	Urinary hesitancy / retention	6	5	1	1	2	2

The estimate of the cumulative risk of adverse events according to the Kaplan-Meier method and log-rank test is significantly higher in the imipramine group compared to placebo ($p = 0.001$) and approaches significance in the reboxetine group compared with placebo ($p = 0.051$). As for individual events or clusters, the cumulative risk is significantly higher on reboxetine than on placebo for insomnia, increased sweating, dry mouth, vertigo and constipation. Similarly, the cumulative risk is significantly higher on imipramine than on placebo for dry mouth, constipation, increased sweating, vertigo, hypotension and related symptoms, tremor and blurred vision.

The log-rank tests on the direct comparison between reboxetine and imipramine in terms of increased risk of adverse events indicate significant differences in favour of reboxetine for dry mouth, hypotension and related symptoms and tremor. A difference in favour of reboxetine, but not a significant one, was also reported of nausea and related symptoms, somnolence and increased sweating, while the difference was in favour for imipramine, but not significantly so, for headache/migraine and urinary hesitancy/retention.

8.2.3 SERIOUS ADVERSE EVENTS, DEATHS AND ADVERSE EVENTS ASSOCIATED WITH WITHDRAWAL

8.2.3.1 Serious Adverse Events and Deaths

There were one death (one patient committed suicide in the imipramine group) and 5 serious adverse events, all occurred in the imipramine- and placebo-treated patients: 2 cases of attempted suicide occurred in the placebo group and 1 case of attempted suicide, 1 case of postural hypotension, dizziness and syncope, 1 case of attention seeking autolesionistic behaviour in the imipramine group. Case histories for these patients are provided in Appendix 12.2.1.

8.2.3.2 Adverse Events Associated with Withdrawal

Thirty-three patients (11 on reboxetine, 9.8%; 15 on imipramine, 13.0% and 7 on placebo, 6.3%) withdrew from the study because of newly emerged adverse events (Table 64). The nature of the adverse events is summarised as follows:

Pharmacia

Document 9550082

Adverse Events Associated with Withdrawal

Treatment	Patient no.	Adverse event	Relationship to study drug
Reboxetine	460, 255, 252, 161	Dry mouth	Probable, Possible, Possible, Possible
	255, 253, 252	Agitation	Possible, Possible, Possible
	334, 143	Increased sweating	Probable, Probable
	510, 163	Vertigo	Possible, Possible
	143	Dyspnoea	Possible
	451	Constipation	Definite
	451	Thrombosed haemorrhoids	None
	460	Confusion	Probable
	161	Urinary tract infection	None
	163	Anxiety	Possible
	163	Tachycardia	Possible
	510	Hypotension	Probable
	510	Insomnia	Possible
	185	Impotence	Definite
	185	Increased gamma-GT	Doubtful
	185	Urinary retention	Definite
	252	Involuntary muscle contractions	Possible
	252	Tremor	Possible
	255	Mydriasis	Doubtful
	255	Pyuria	None
	334	Chest pain	Probable
	334	Dizziness	Probable
	334	Paraesthesia	Probable

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Pharmacia

Document 9550082

Treatment	Patient no.	Adverse event	Relationship to study drug
Imipramine	461, 456, 371, 254, 151	Dry mouth	Possible, Probable, Possible, Possible, Possible
	456, 183, 151, 100, 16	Increased sweating	Probable, Possible, Possible, Possible, Probable
	461, 116, 100, 16	Nausea	Possible, Possible, Possible, Possible
	461, 80, 11	Dizziness	Possible, Possible, Definite
	254, 183, 100	Tremor	Possible, Unknown, Possible
	375, 213, 191	Suicide attempt/ideation	Possible, None, None
	151, 11	Postural hypotension	Possible, Definite
	375, 80	Abnormal vision	Doubtful, Possible
	462, 254	Insomnia	Possible, Possible
	116, 100	Vertigo	Possible, Possible
	456	Constipation	Probable
	456	Precordial chest pain	Possible
	456	Syncope	Possible
	456	Tachycardia	Probable
	462	Depersonalisation	Possible
	462	Hyperkinesia	Possible
	116	Headache	Possible
	151	Asthenia	Possible
	183	Abdominal pain	None
	183	Agitation	Unknown
	183	Colitis	Unknown
	183	Dysphagia	Unknown
	183	Paraesthesia	Unknown
183	Rigors	Unknown	
183	Tinnitus	Definite	
16	Hot flushes	Probable	

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Pharmacia

Document 9550082

Treatment	Patient no.	Adverse event	Relationship to study drug
Placebo	241, 83	Agitation	Possible, Possible
	99, 83	Diarrhoea	Possible, Possible
	179, 176	Suicide attempt	Unknown, None
	6	Abdominal pain	Possible
	6	Arthralgia	Doubtful
	6	Constipation	Probable
	6	Dry mouth	Definite
	6	Flatulence	Doubtful
	6	Micturition disorder	Definite
	6	Nausea	Possible
	6	Paroniria	Unknown
	6	Rash	Possible
	6	Taste perversion	Unknown
	83	Insomnia	Possible
	83	Tremor	Possible
	99	Dyspepsia	Possible
	176	Aggravated depression	None
	241	Hyperkinesia	Possible
	246	Bradycardia	Probable

Patient No 213 from the imipramine group died by suicide.

In addition, two patients dropped out the study due to intercurrent medical problems without having a newly emerged adverse event form filled in the CRF: one patient (No 416 from the reboxetine group) dropped out due to the discovery of hypothyroidism which was present before the start of treatment, and a second patient (No 138 from the placebo group) due to bad hepatic function.

8.3 Laboratory Tests

8.3.1 SUMMARY STATISTICS OF LABORATORY VALUES

As shown in Table 65, in the reboxetine group, compared to baseline, there was a significant ($p < 0.01$) decrease after 6 weeks of treatment in total cholesterol (median difference -10.88 mg/dl). After 3 weeks of treatment, there were no such significant differences.

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Similarly, in the imipramine group, compared to baseline, there was a significant decrease after 3 weeks of treatment in lymphocytes (median difference -1.00%) and chloride (median difference -0.89 mEq/l), whilst there was a significant increase in creatinine after 3 weeks of treatment (median difference 0.03 mg/dl) and in alkaline phosphatase after 6 weeks of treatment (median difference 7.92 U/l). In the placebo group, compared to baseline, there was a significant decrease in gamma GT after 3 weeks of treatment (median difference -1.91 U/l) and in total cholesterol after 6 weeks of treatment (median difference -10.00 mg/dl).

8.3.2 URINALYSIS

Frequency of abnormal findings at baseline and during the treatment period or at last assessment, are shown in Table 66 and 67, respectively. No indication of increased frequencies of abnormal findings as compared to baseline emerges. In fact, there is no indication of increased proportions of patients shifted from absence to presence of albumin, sugar, WBC and RBC as compared to baseline both at the various assessment intervals (Table 68) and at the last available assessment (Table 69). The same considerations hold for specific gravity (Tables 70 and 71).

8.3.3 ABNORMAL LABORATORY VALUES

The number and percentage of patients shifted from values within, below or above the normal range to values within, below or above the latter are given by period in Table 72. In the imipramine group, a statistically significant shift in the distribution of the frequencies toward lower values was found for eosinophils and calcium after 3 weeks of treatment, and higher values for SGPT after 6 weeks of treatment ($p < 0.01$; Maxwell's test). In the reboxetine group, a statistically significant shift in the distribution of the frequencies toward lower values was found for total cholesterol after 6 weeks of treatment ($p < 0.01$; Maxwell's test). There were no statistically significant shifts ($p < 0.01$) in the distribution of the frequencies (either towards the higher or lower values) in the placebo group.

8.3.4 ABNORMAL LABORATORY VALUES OF CLINICAL RELEVANCE

The distribution pattern of patients with clinically relevant abnormal values is given by variable and period of treatment in Table 73. Frequency of clinically relevant abnormal values was similarly low in the three treatment groups over the study period; no significantly increased frequency over baseline was present for any of the variables measured in the reboxetine, imipramine and placebo patient groups.

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Document 9550082

8.4 Vital Signs

8.4.1 BLOOD PRESSURE AND HEART RATE

Summary statistics of blood pressure and heart rate values and changes vs baseline at each visit during the study are presented in Tables 74 to 78. There were no important trends apparent in mean and median blood pressure and heart rate values and changes during the study.

The absolute and per cent frequency of patients at each visit showing a modification of 20% or more vs baseline is given in Table 75, while the absolute frequency of patients showing such a modification accompanied by absolute critical values (≥ 160 or ≤ 100 mmHg for systolic blood pressure; ≥ 100 or ≤ 70 mmHg for diastolic blood pressure; ≥ 100 or ≤ 50 beats/min for heart rate) are given in Table 76, together with their frequency (once, twice or more times) during the study (Table 77).

The proportion of patients showing an increase and a decrease of possible clinical relevance for the systolic and diastolic blood pressure in lying and standing position was similar in all groups. As for the lying and standing heart rate, a slightly higher proportion of patients with at least 20% increased values vs baseline, as well as such increases associated with values ≥ 100 beats/min was observed during the whole treatment period in both active treatment groups compared with placebo treatment group. The same results were observed in patients who had clinically relevant increase at least once during the treatment period. A total of 11 and 13 patients in the two positions, respectively, in the reboxetine group (10.4% of 106 evaluated patients [lying position] and 12.4% of 105 evaluated patients [standing position]) and a total of 5 and 8 patients in the two positions, respectively, in the imipramine group (5.0% of 100 evaluated patients [lying position] and 8.1% of 99 evaluated patients [standing position]) had relevant increased values compared with a total of 1 and 2 patients in the two positions, respectively, in the placebo group (1.0% of 104 evaluated patients [lying] and 1.9% of 105 evaluated patients [standing]) (Table 77).

The number and percentage of patients with orthostatic hypotension at each visit is presented in Table 78. At baseline the event was present in 3 patients of the reboxetine group, while it was absent in the imipramine and placebo groups. Subsequently, the event had a low frequency at all visits, affecting a maximum of 4.6% of the reboxetine patients on Day 42, 3.6% of the imipramine patients on Day 7 and 2.0% of the placebo patients on Day 14.

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Document 9550082

8.4.2 BODY WEIGHT

Summary statistics of the body weight values (Kg) during the study are given in Tables 79 and 80, respectively. No trends toward modification and no difference between the reboxetine, imipramine and placebo groups were apparent.

8.4.3 BODY TEMPERATURE

Individual data are reported in Appendix 12.2.2, Listing 20.0. No modifications of note were evident.

8.5 Electrocardiogram

As shown in Table 81, 277 patients had their ECG recorded at baseline. Of these patients, 16.5% on reboxetine, 15.4% on imipramine and 10.5% on placebo showed at least one ECG abnormality. During the study, 252 patients had their ECG recorded after 3 weeks of treatment, and 236 after 6 weeks of treatment. Of these patients, in the reboxetine group, 15.1% (after 3 weeks) and 12.7% (after 6 weeks) had at least one ECG abnormality recorded during treatment. The equivalent proportions in the imipramine group were 27.5% (after 3 weeks) and 18.7% (after 6 weeks) and in the placebo group 14.0% (after 3 weeks) and 11.0% (after 6 weeks). As shown in Table 82, during the study, the frequency of normalisation of ECG recordings in patients with at least one abnormality at entry was always similar to or higher than the frequency of at least one newly emerged abnormality in patients with normal tracing at baseline in all the treatment groups. At last assessment of the study (Table 83), of the 39 patients (15 reboxetine, 14 imipramine and 10 placebo) who had had at least one abnormality at baseline, 33.3% of reboxetine, 28.6% of imipramine and 40.0% of placebo patients were reported as normal. Among the 238 patients (76 reboxetine, 77 imipramine and 85 placebo) with normal tracings at baseline, 2.6% of reboxetine, 14.3% of imipramine and 5.9% of placebo patients showed at least one abnormality during the study.

The frequency of individual abnormalities at admission and during the study is shown by treatment group in Table 84. At screening, among the individual abnormalities, the most frequent was sinus bradycardia with a maximum of 5.5% of the 91 evaluated cases of the reboxetine group, 4.4% of the 91 evaluated cases in the imipramine group, and 3.2% of the 95 evaluated cases in the placebo group. During treatment, the frequencies of all observed abnormalities were not modified to any significant extent in either treatment group. As shown in Table 85, at last assessment, for all abnormalities and treatment groups, the proportion of newly observed cases among normal baseline cases is similar or lower than the proportion of normalised cases among abnormal baseline cases. Newly emerged abnormalities never reported at baseline occurred in rare cases and with a higher frequency in the imipramine group than in the reboxetine and placebo groups (13 of 91 evaluated vs 7

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Document 9550082

of 95 and 3 of 91 evaluated newly cases on imipramine, placebo and reboxetine, respectively). The between treatment group difference was due especially to sinus tachycardia, which occurred more in imipramine (7 new cases) than in reboxetine (2 new cases) and in placebo (0 cases) patients.

The frequencies of randomised patients with at least one abnormality by abnormality group during the study is shown in Table 86. At screening, from 1.1% (conduction disorders) to 8.8% (rhythm disorders) of the evaluated patients in the reboxetine group, 1.1% (other disorders) to 7.7% (rhythm disorders) in the imipramine group and 1.1% (other disorders) to 4.2% (rhythm disorders) in the placebo group showed at least one abnormality of the indicated groups. During treatment, the frequencies were not modified to any significant extent in any of the treatment groups, except for conduction disorders, which from 4.4% at screen increased to 8.8% after 3 weeks of treatment and to 6.7% after 6 weeks of treatment in the imipramine group, as well as for rhythm disorders, which, from 7.7% at screen, increased to 12.5% after 3 weeks of treatment and 10.7% after 6 weeks of treatment in the imipramine group and, from 4.2% at screen, to 9.3% and 8.5% after 3 and 6 weeks of treatment in the placebo group. As shown in Table 87, at last assessment, the proportion of newly emerged cases was similar in all treatment groups, and in all groups was far lower than the proportion of normalised cases, except for abnormalities of rhythm and conduction disorders. In the first case, the abnormalities occurred slightly more frequently in the imipramine- (8 new cases of 91 evaluated) than in the reboxetine-(3 new cases of 91 evaluated) and placebo-treated patients (5 new cases of 95 evaluated), while in the second case the abnormalities occurred only in the imipramine-treated patients (3 new cases of the 91 evaluated).

8.6 Safety Conclusions

All the 339 patients who received study treatment were included in the safety analysis (112 reboxetine, 115 imipramine, 112 placebo).

The occurrence of newly reported adverse events was higher in the imipramine group than in the reboxetine or placebo groups during the study; 71/112 reboxetine group patients reported 211 adverse events compared with 81/115 imipramine patients who reported 288 adverse events and 58/112 placebo group patients who reported 141 adverse events. The cumulative risk of occurrence of adverse events was significantly higher in the imipramine group compared to placebo ($p = 0.001$) and approached significance in the reboxetine group ($p = 0.051$), while the risk of developing at least one adverse event was similar in the reboxetine and the imipramine groups.

The prevalence of adverse events during the study indicated a higher proportion of patients with adverse events in both imipramine and reboxetine groups than in placebo group during

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Document 9550082

the whole treatment period. In addition, the proportion was always slightly higher on imipramine than on reboxetine, particularly during the fourth and the sixth week.

Thirty-three patients (11 on reboxetine, 9.8%; 15 on imipramine, 13.0% and 7 on placebo, 6.3%) withdrew from the study because of adverse events. One patient of the imipramine group died by suicide. In addition, two patients dropped out of the study due to intercurrent medical problems without having a newly emerged adverse event form filled in the CRF: one patient (No 416 from the reboxetine group) dropped out due to the discovery of hypothyroidism which was present before the start of treatment, and a second one (No 138 from the placebo group) due to bad hepatic function.

Most frequently reported adverse events were: dry mouth (25.0% reboxetine, 42.6% imipramine and 12.5% placebo); constipation (15.2%, 15.7%, 5.4%, respectively) and increased sweating (12.5%, 19.1%, 2.7%, respectively). The majority of adverse events were moderate in all treatment groups. Adverse events were reported with a similar frequency by women and men in all treatment groups.

The most relevant between-gender differences were related to the frequency of dry mouth, constipation, increased sweating, and nausea, complained of mainly by female patients (27%, 46%, 19% dry mouth; 17%, 18%, 9% constipation; 16%, 21%, 4% increased sweating; 10%, 17%, 17% nausea and related symptoms) on reboxetine, imipramine and placebo, respectively. The corresponding figures for male patients were 21%, 37%, 7% dry mouth; 12%, 11%, 2% constipation; 7%, 16%, 2% increased sweating; 7%, 11%, 2% nausea and related symptoms on reboxetine, imipramine and placebo, respectively. Tremor was complained of by more female than male patients (21% vs 11%) on imipramine but not on placebo (4% of female patients vs 5% of male patients) and on reboxetine (6% vs 5% of female and male patients, respectively). Conversely, urinary hesitancy/retention was complained of by more male than female patients on reboxetine (14% vs 0%, respectively), but not by patients on imipramine and placebo (0% and 2% vs 1% and 2% of male and female patients, respectively).

The estimate of the cumulative risk of adverse events according to the Kaplan-Meier method and log-rank test is significantly higher in the imipramine group compared to placebo ($p = 0.001$) and approaches significance in the reboxetine group compared with placebo ($p = 0.051$). As for individual events or clusters, the cumulative risk is significantly higher on reboxetine than on placebo for insomnia, increased sweating, dry mouth, vertigo and constipation. Similarly, the cumulative risk is significantly higher on imipramine than on placebo for dry mouth, constipation, increased sweating, vertigo, hypotension and related symptoms, tremor and blurred vision.

The log-rank tests on the direct comparison between reboxetine and imipramine in terms of increased risk of adverse events indicate significant differences in favour of reboxetine for

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Document 9550082

dry mouth, hypotension and related symptoms and tremor. A difference in favour of reboxetine, but not a significant one, was also reported for nausea and related symptoms, somnolence and increased sweating, while the difference was in favour of imipramine, but not significantly so, for headache/migraine and urinary hesitancy/retention.

In addition to the mentioned death (suicide) in the imipramine group, 5 serious adverse events, all occurred in the imipramine- and placebo-treated patients were reported: 2 cases of attempted suicide occurred in the placebo group and 1 case of attempted suicide, 1 case of postural hypotension, dizziness and syncope and 1 case of attention seeking autolesionistic behaviour in the imipramine group.

There was no indication of modifications in laboratory tests that were of clinical significance.

Vital signs were not modified to any significant extent. The proportion of patients showing an increase and a decrease of possible clinical relevance for the systolic and diastolic blood pressure in lying and standing position was similar in all groups. As for the lying and standing heart rate, a slightly higher proportion of patients with at least 20% increased values vs baseline, as well as such increases associated with values ≥ 100 beats/min was observed during the whole treatment period in both active treatment groups compared with the placebo treatment group. The same results were observed in patients who had clinically relevant increase at least once during the treatment period. A total of 11 and 13 patients in the two positions, respectively, in the reboxetine group (10.4% of 106 evaluated patients [lying position] and 12.4% of 105 evaluated patients [standing position]) and a total of 5 and 8 patients in the two positions, respectively, in the imipramine group (5.0% of 100 evaluated patients [lying position] and 8.1% of 99 evaluated patients [standing position]) had relevant increased values compared with a total of 1 and 2 patients in the two positions, respectively, in the placebo group (1.0% of 104 evaluated patients [lying] and 1.9% of 105 evaluated patients [standing]).

No indication of effect on cardiac function emerged from ECG recordings. Newly emerged abnormalities never reported at baseline occurred in rare cases and with a higher frequency in the imipramine group than in the reboxetine and placebo groups (13 of 91 evaluated vs 7 of 95 and 3 of 91 evaluated newly cases on imipramine, placebo and reboxetine, respectively). The between treatment group difference was due especially to sinus tachycardia, which occurred more in imipramine (7 new cases) than in reboxetine (2 new cases) and in placebo (0 cases) patients. During treatment, the frequencies were not modified to any significant extent in any of the treatment groups, except for conduction disorders, which from 4% at screen increased to 9% after 3 weeks of treatment and to 7% after 6 weeks of treatment in the imipramine group, as well as for rhythm disorders, which, from 8% at screen, increased to 13% after 3 weeks of treatment and 11% after 6 weeks of

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Document 9550082

treatment in the imipramine group and, from 4% at screen, to 9% both after 3 and 6 weeks of treatment in the placebo group. At last assessment, the proportion of newly emerged cases was similar in all treatment groups, and in all groups was far lower than the proportion of normalised cases, except for abnormalities of rhythm and conduction disorders. In the first case, the abnormalities occurred slightly more frequently in the imipramine- (8 new cases of 91 evaluated) than in the reboxetine-(3 new cases of 91 evaluated) and placebo-treated patients (5 new cases of 95 evaluated), while in the second case the abnormalities occurred only in the imipramine-treated patients (3 new cases of the 91 evaluated).

9. DISCUSSION

Three hundred and thirty-nine patients were admitted to the study from January 1991 to October 1992 and randomised to treatment by investigators at 34 centres. A total of 252 patients (74.3%) completed the study and 87 (25.7%) withdrew (3 of them, 2 in the imipramine and 1 in the placebo group, having the last assessment at Day 42 visit); 23 (20.5%) in the reboxetine group, 38 (33.0%) in the imipramine groups, and 26 (23.2%) in the placebo group.

Newly emerged adverse events or intercurrent illnesses were the main reasons for withdrawal in 11, 15 and 7 patients of the reboxetine, imipramine and placebo groups, respectively. One patient from the imipramine group died by suicide.

The majority of patients, in the reboxetine and imipramine groups, were female, and the proportion of females and males was similar in the placebo group. The vast majority of patients were Caucasian. All treatment groups were well matched for age, height, weight and race. Recurrent Major Depressive Disorder (DSM-III-R No 296.3) was diagnosed for the majority of patients in each treatment group (68% reboxetine, 70% imipramine, and 73% placebo). A Major Depression First Episode (DSM-III-R No 296.2) was diagnosed in almost all remaining cases, except for 2 patients (1 reboxetine and 1 imipramine) who were diagnosed as Bipolar Disorder, Depressed, unspecified (DSM-III-R No 296.5). The treatment groups were well matched with regard to all the tests characterising the history of mental disorders.

In the 110 patients randomised to reboxetine who had at least one assessment in addition to baseline, the mean HAMD total score was reduced from 27.5 at Day 0 to 14.0 at last assessment, and to 11.3 at Day 42 in the 89 patients assessed at Day 42. In the 111 patients randomised to imipramine with at least one assessment in addition to baseline, the mean HAMD total score was reduced from 26.9 at Day 0 to 13.2 at last assessment, and to 9.4 at Day 42 (79 patients). Mean HAMD total score in the 111 patients randomised to placebo was reduced from 27.1 at Day 0 to 15.8 at last assessment, and to 13.1 at Day 42 (87 patients). The results of the planned analysis of the study end-point indicate slightly higher

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improvement on both reboxetine and imipramine, compared to placebo, though the differences do not reach statistical significance ($p > 0.025$, one-tailed test).

The results of the planned analysis of the study end-point, i.e. the difference vs baseline of the HAMD total score at last assessment, do not allow the refusal of the null hypothesis of no difference between reboxetine and placebo. Though the positive control, imipramine, resulted similarly not different from placebo in terms of extent of the induced clinical improvement.

This finding is not surprising. Reviews of placebo-controlled studies carried out with tricyclic antidepressants, including imipramine, have shown that the variability of placebo associated response is very high. In view of this, a not irrelevant proportion of the controlled studies comparing imipramine to placebo failed to detect statistically significant differences [27]. However, as in our case for both reboxetine and imipramine, the direction of the difference of outcome is almost always in favour of the active treatments [28].

At last assessment, 59.1% of the reboxetine-treated patients, 62.2% of the imipramine-treated patients and 52.3% of the placebo-treated patients were classified as responders, while 42.7%, 50.5% and 36.0%, respectively, were seen to be in remission. The between treatment difference in the proportion of remissions and responders both for imipramine and reboxetine compared with placebo did not reach the statistical significance ($p > 0.025$). Patients on imipramine had showed a cumulative response over time (Kaplan-Meier method) significantly higher ($p = 0.0055$) than patients on placebo while patients on reboxetine had a rate of response whose difference from placebo didn't reach significance ($p = 0.081$).

Additional analyses were carried out in the sub-populations of melancholic (DSM IV criteria) and severe (CGI- Severity of Illness: marked to extreme ill at the admission) patients. In the former case, with respect to the total population, the improvement on both active treatments was maximal and on placebo it was minimal. The mean decrease in the two active treatment groups was very similar, the mean difference between imipramine and reboxetine being of 0.12 points (95% C.I.: $-3.2 \div 3.4$). However, the difference between active treatments and placebo was statistically significant ($p < 0.025$) only for imipramine. In melancholic patients the difference between placebo and active treatments was significantly superior for reboxetine, but not for imipramine. In fact, the mean difference between active treatments was in favour of reboxetine with a value of 3.9 points (95% C.I.: $-0.5 \div 8.3$).

The CGI severity of illness had decreased in 77.3% and 77.5% of the reboxetine and imipramine patients, respectively, compared with 65.8% of the placebo patients, increased in 5.5% and 4.5% of the reboxetine and imipramine patients, respectively, compared with 8.1% of the placebo patients, and had remained the same in the 17.3% and 18.1% of

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Document 9550082

reboxetine and imipramine patients, respectively, compared with 26.1% of the placebo patients. The clearest difference between treatments is related to the percentage of patients who were 'very much improved' at last assessment. This was higher in the reboxetine group (29.1%) and the imipramine group (28.8%) compared with the placebo group (17.1%). In addition, the percentage of patients with 'no change' was higher in the placebo group (17.1%) than in the reboxetine group (9.1%) and the imipramine group (10.8%).

At last assessment, side-effects were judged to outweigh efficacy in 15.3% of the reboxetine patients, 16.2% of the imipramine patients and in 13.5% of the placebo patients. The most relevant placebo-active treatment group differences in the Efficacy Index are seen in the proportion of cases where no advantage in terms of efficacy vs side-effects was identified (index = 1): 21.6% of the placebo-treated cases compared with 13.5% of the reboxetine-treated and 13.5% of the imipramine-treated cases. It was also seen in the proportion of cases where efficacy outweighed side-effects (index = 4): 22.5% of the placebo-treated cases compared with 28.8% of the reboxetine-treated cases and only 14.4% of the imipramine-treated cases.

The mean total MADRS score was reduced from 16.4 at Day 0 to 8.4 at last assessment in the 110 reboxetine group patients with at least one assessment in addition to baseline, and to 6.6 at Day 42 in the 89 reboxetine patients who completed the study. In patients randomised to imipramine, values changed from 16.7 at Day 0 to 8.2 at last assessment (111 patients), and to 5.8 at Day 42 (79 assessed patients). The corresponding reductions in placebo group patients were from 16.3 at Day 0 to 9.8 at last assessment (111 patients) and to 7.7 at Day 42 (87 assessed patients).

All the 339 patients who received study treatment were included in the safety analysis (112 reboxetine, 115 imipramine, 112 placebo).

Safety and tolerability were assessed by the reporting of any adverse event and assessment of vital signs (supine and standing blood pressure and heart rate), laboratory tests, and ECG. For clinical and laboratory tests were analysed only patients with at least one assessment in addition to baseline.

The occurrence of newly reported adverse events was higher in the imipramine group than in the reboxetine or placebo groups during the study; 71/112 reboxetine group patients reported 211 adverse events compared with 81/115 imipramine patients who reported 288 adverse events and 58/112 placebo group patients who reported 141 adverse events.

The prevalence of adverse events during the study indicated a higher proportion of patients with adverse events in the both imipramine and reboxetine groups than in the placebo group during the whole treatment period. In addition, the proportion was always slightly higher on imipramine than on reboxetine, particularly during the fourth and the sixth week.

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Document 9550082

Most frequently reported were: dry mouth (25.0% reboxetine, 42.6% imipramine and 12.5% placebo); constipation (15.2%, 15.7%, 5.4%) and increased sweating (12.5%, 19.1%, 2.7%). In addition, events reported with different frequencies in the three groups were: insomnia (11% on reboxetine, 7% on imipramine, 4% on placebo), vertigo (5% and 6% on reboxetine and imipramine, 0% on placebo), tremor (5% on reboxetine and placebo, 17% on imipramine), hypotension and related symptoms (9% on reboxetine, 17% on imipramine, 5% on placebo) blurred vision (9% on imipramine, 5% on reboxetine, 3% on placebo). The majority of adverse events were moderate in all treatment groups. Adverse events were reported with a similar frequency by women and men in all treatment groups. The most significant between-gender differences were related to the frequency of dry mouth, constipation, increased sweating, and nausea and related symptoms, complained of mainly by female patients.

The estimate of the cumulative risk of adverse events according to the Kaplan-Meier method and log-rank test was significantly higher in the imipramine group compared to placebo ($p = 0.001$) and approached significance in the reboxetine group compared with placebo ($p = 0.051$). As for individual events, the cumulative risk was higher on reboxetine (as well as imipramine) than on placebo for dry mouth, increased sweating, constipation and vertigo, while it was higher on reboxetine (but not on imipramine) than on placebo for insomnia and it was higher on imipramine (but not reboxetine) than on placebo for hypotension and related symptoms, tremor and blurred vision.

The log-rank tests on the direct comparison between reboxetine and imipramine in terms of increased risk of adverse events indicate significant differences in favour of reboxetine for dry mouth, hypotension and related symptoms and tremor. A difference in favour of reboxetine, although not a significant one, was also reported for nausea and related symptoms, somnolence and increased sweating, while the difference was in favour of imipramine, but not significantly so, for headache/migraine and urinary hesitancy/retention.

In addition to the mentioned death (suicide) in the imipramine group, 5 serious adverse events, all occurred in the imipramine-and placebo-treated patients were reported: 2 cases of attempted suicide occurred in the placebo group and 1 case of attempted suicide, 1 case of postural hypotension, dizziness and syncope and 1 case of attention seeking autolesionistic behaviour in the imipramine group.

There was no indication of modifications in laboratory tests that were of clinical significance.

Vital signs were not modified to any significant extent, with the exception of the lying and standing heart rate, for which a slightly higher proportion of patients with at least 20% increased values vs baseline as well as such increases associated with values ≥ 100 beats/min, was observed during the whole treatment period in both active treatment groups compared

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Document 9550082

with the placebo treatment group. The same results were observed in patients who had clinically relevant increased at least once during the treatment period. The proportions of patients showing an increase and a decrease of possible clinical relevance for the systolic and diastolic blood pressure in lying and standing position was similar in all groups.

No indication of effect on cardiac function emerged from ECG recordings. The proportion of newly emerged abnormal ECG recordings was lower than the frequency of normalisation of readings classified as abnormal at baseline in all groups. Newly emerged abnormalities never reported at baseline occurred in rare cases and with a higher frequency in the imipramine group than in the reboxetine and placebo groups (13 of 91 evaluated vs 7 of 95 and 3 of 91 evaluated newly cases on imipramine, placebo and reboxetine, respectively). The between treatment group difference was due especially to sinus tachycardia, which occurred more in imipramine (7 new cases) than in reboxetine (2 new cases) and in placebo (0 cases) patients. During treatment, the frequencies were not modified to any significant extent in any of the treatment groups, except for conduction disorders, which from 4% at screen increased to 9% after 3 weeks of treatment and to 7% after 6 weeks of treatment in the imipramine group, as well as for rhythm disorders, which, from 8% at screen, increased to 13% after 3 weeks of treatment and 11% after 6 weeks of treatment in the imipramine group and, from 4% at screen, to 9% both after 3 and 6 weeks of treatment in the placebo group. At last assessment, the proportion of newly emerged cases was similar in all treatment groups, and in all groups was far lower than the proportion of normalised cases, except for abnormalities of rhythm and conduction disorders. In the first case, the abnormalities occurred slightly more frequently in the imipramine- (8 new cases of 91 evaluated) than in the reboxetine-(3 new cases of 91 evaluated) and placebo-treated patients (5 new cases of 95 evaluated), while in the second case the abnormalities occurred only in the imipramine-treated patients (3 new cases of the 91 evaluated).

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10. CONCLUSION

The results of the statistical analysis of the study end-point do not allow the refusal of the null hypothesis of no difference between both active treatments and placebo. However, indications on the higher efficacy of the active treatments compared to placebo derive from the analysis of the cumulative rate of response in according to the Kaplan-Meier method in the total population, particularly in the case of imipramine, and from the sub-population analyses in severe and melancholic patients, for both reboxetine and imipramine.

The safety profiles of reboxetine and imipramine compared to placebo were similar with regard to vital signs, haematology and blood chemistry tests and ECG examinations. The cumulative risk of adverse events was significantly higher on imipramine compared to placebo and approached significance on reboxetine compared with placebo. As for individual events, the cumulative risk was higher on reboxetine (as well as imipramine) than on placebo for dry mouth, increased sweating, constipation and vertigo, while it was higher on reboxetine (but not on imipramine) than on placebo for insomnia. The direct comparison between reboxetine and imipramine in terms of increased risk of adverse events indicated significant differences always in favour of reboxetine (dry mouth, hypotension and related symptoms and tremor).

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Pharmacia

Document 9550082

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Pharmacia

Document 9550082

TABLES

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012/4/015

TABLE No. : 1

NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT

Centre/Assigned treatment	Screen	Visit												
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
1	Imipramine	8	8	7	6	6	6	6						
	Placebo	5	5	5	5	5	5	5						
	Reboxetine	6	6	6	5	4	4	4						
2/1	Imipramine	1	1	1	1	1	1	1						
	Placebo	1	1	1	1	1	1	1						
	Reboxetine	1	1	1	1	1	1	1						
2/2	Imipramine	2	2	2	2	2	2	2						
	Placebo	2	2	2	2	2	2	2						
	Reboxetine	2	2	2	2	2	2	2						
2/3	Imipramine	3	3	3	3	3	3	3						
	Placebo	2	2	2	2	2	2	2						
	Reboxetine	2	2	2	2	2	2	2						
2/4	Imipramine	2	2	2	2	2	2	2						
	Placebo	2	2	2	2	2	2	2						
	Reboxetine	2	2	2	2	2	2	2						
2/5	Imipramine	2	2	2	2	2	2	2						
	Placebo	2	2	2	2	2	2	2						
	Reboxetine	2	2	2	2	2	2	2						
2/6	Imipramine	2	2	2	2	2	2	2						
	Placebo	2	2	2	2	2	2	2						
	Reboxetine	2	2	2	2	2	2	2						
3/1	Imipramine	6	6	6	6	6	6	6						
	Placebo	6	6	6	6	6	6	6						
	Reboxetine	6	6	6	6	6	6	6						

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 1

NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT

Centre/Assigned treatment	Screen	Visit												
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
3/2	Reboxetine	1	1	1	1	1	1	1	1	1	1	1	1	
	Imipramine	2	2	2	2	2	2	2	2	2	2	2	2	
	Placebo	2	2	2	2	2	2	2	2	2	2	2	2	
	Reboxetine	2	2	2	2	2	2	2	2	2	2	2	2	
3/4	Imipramine	6	6	6	6	6	6	6	6	6	6	6	6	
	Placebo	6	6	6	6	6	6	6	6	6	6	6	6	
	Reboxetine	6	6	6	6	6	6	6	6	6	6	6	6	
	Imipramine	6	6	6	6	6	6	6	6	6	6	6	6	
4/1	Reboxetine	6	6	6	6	6	6	6	6	6	6	6	6	
	Imipramine	6	6	6	6	6	6	6	6	6	6	6	6	
	Placebo	6	6	6	6	6	6	6	6	6	6	6	6	
	Reboxetine	6	6	6	6	6	6	6	6	6	6	6	6	
4/2	Reboxetine	2	2	2	2	2	2	2	2	2	2	2	2	
	Placebo	2	2	2	2	2	2	2	2	2	2	2	2	
	Reboxetine	1	1	1	1	1	1	1	1	1	1	1	1	
	Imipramine	2	2	2	2	2	2	2	2	2	2	2	2	
4/3	Placebo	2	2	2	2	2	2	2	2	2	2	2	2	
	Reboxetine	1	1	1	1	1	1	1	1	1	1	1	1	
	Imipramine	4	4	4	4	4	4	4	4	4	4	4	4	
	Placebo	4	4	4	4	4	4	4	4	4	4	4	4	
4/4	Reboxetine	4	4	4	4	4	4	4	4	4	4	4	4	
	Imipramine	2	2	2	2	2	2	2	2	2	2	2	2	
	Placebo	2	2	2	2	2	2	2	2	2	2	2	2	
	Reboxetine	2	2	2	2	2	2	2	2	2	2	2	2	
5/1	Reboxetine	1	1	1	1	1	1	1	1	1	1	1	1	
	Imipramine	4	4	4	4	4	4	4	4	4	4	4	4	
	Placebo	4	4	4	4	4	4	4	4	4	4	4	4	
	Reboxetine	4	4	4	4	4	4	4	4	4	4	4	4	
5/2	Reboxetine	2	2	2	2	2	2	2	2	2	2	2	2	
	Imipramine	1	1	1	1	1	1	1	1	1	1	1	1	
	Placebo	2	2	2	2	2	2	2	2	2	2	2	2	
	Reboxetine	2	2	2	2	2	2	2	2	2	2	2	2	
5/3	Reboxetine	1	1	1	1	1	1	1	1	1	1	1	1	
	Imipramine	2	2	2	2	2	2	2	2	2	2	2	2	
	Placebo	1	1	1	1	1	1	1	1	1	1	1	1	
	Reboxetine	1	1	1	1	1	1	1	1	1	1	1	1	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 1

NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT

Centre/Assigned treatment	Visit												
	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
5/3	2	2	2	1									
	2	2	2	2	2	2	2	2					
	2	2	2										
6/1	2	2	2	2	2	2	2	1					
	2	2	2	2	2	2	2	2					
	4	4	4	4	4	4	3	3					
6/2	4	4	4	3	2	2	2	2					
	4	4	4	4	4	4	4	3					
	4	4	4	4	4	4	4	3					
6/3	6	6	6	6	5	5	5	4					
	5	5	5	4	4	4	4	4					
	4	4	4	2	2	1	1	1					
7/02	2	2	2	2	2	2	2	1					
	3	3	3	3	3	3	3	3					
	3	3	3	3	3	3	3	2					
7/03	4	4	4	4	4	4	4	4					
	4	4	4	4	4	4	4	4					
	4	4	4	4	4	4	4	4					
7/04	4	4	4	4	4	4	4	4					
	4	4	4	4	4	4	4	4					
	4	4	4	4	4	4	4	4					
7/05	4	4	4	4	4	4	4	4					
	4	4	4	4	4	4	4	4					
	4	4	4	4	4	4	4	4					
7/07	2	2	2	2	2	2	2	1					
	2	2	2	2	2	2	2	1					
	2	2	2	2	2	2	2	1					

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 1

NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT

Centre/Assigned treatment	Visit										
	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63
7/07	2	2	2	2	2	2	2	2	2	2	2
	2	2	2	2	2	2	2	2	2	2	2
	8	8	8	8	8	8	8	8	8	8	8
8	8	8	8	8	8	8	8	8	8	8	8
	8	8	8	8	8	8	8	8	8	8	8
	8	8	8	8	8	8	8	8	8	8	8
8/A	3	3	3	3	3	3	3	3	3	3	3
	3	3	3	3	3	3	3	3	3	3	3
	4	4	4	4	4	4	4	4	4	4	4
9	6	6	6	6	6	6	6	6	6	6	6
	6	6	6	6	6	6	6	6	6	6	6
	6	6	6	6	6	6	6	6	6	6	6
11	7	7	7	7	7	7	7	7	7	7	7
	6	6	6	6	6	6	6	6	6	6	6
	7	7	7	7	7	7	7	7	7	7	7
12	3	3	3	3	3	3	3	3	3	3	3
	3	3	3	3	3	3	3	3	3	3	3
	3	3	3	3	3	3	3	3	3	3	3
13	3	3	3	3	3	3	3	3	3	3	3
	4	4	4	4	4	4	4	4	4	4	4
	3	3	3	3	3	3	3	3	3	3	3
14	2	2	2	2	2	2	2	2	2	2	2
	1	1	1	1	1	1	1	1	1	1	1
	4	4	4	4	4	4	4	4	4	4	4
15	6	6	6	6	6	6	6	6	6	6	6
	5	5	5	5	5	5	5	5	5	5	5
	5	5	5	5	5	5	5	5	5	5	5

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9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No. : 1

NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT

Centre/Assigned treatment	Visit										
	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63
15	4	4	4	4	4	4	4	4	4	4	4
Reboxetine	115	115	115	102	96	88	85	80	85	85	80
Imipramine	112	112	111	106	100	96	88	87	88	88	87
Placebo	112	112	112	106	100	97	92	89	92	92	89
Total	339	339	338	314	296	281	265	256	265	265	256

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 20124/015
TABLE No. : 2
PATIENT DISPOSITION

	Treatment assigned										Total	
	Imipramine		Placebo				Reboxetine					
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Screened	115	100.00	112	100.00	112	100.00	112	100.00	339	100.00	339	100.00
Exposed	115	100.00	112	100.00	112	100.00	112	100.00	339	100.00	339	100.00
Completed	77	66.96	86	76.79	86	76.79	89	79.46	252	74.34	252	74.34
Dropped	38	33.04	26	23.21	26	23.21	23	20.54	87	25.66	87	25.66

PHARMACIA CNS R&D 550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 3

END OF STUDY: REASONS FOR DISCONTINUATION AND VISIT AT WHICH DISCONTINUATION OCCURRED, BY ASSIGNED TREATMENT

Assigned treatment / Reasons		Last visit															
		Total		Day 0		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Imipramine	ADVERSE EVENT (*)	14	100			6	42.9	3	21.4	3	21.4					2	14.3
	DEATH	1	100			1	100										
	LOST TO FOLLOW UP	2	100			2	100										
	DETERIORATION	11	100			1	9.1	3	27.3	3	27.3	1	9.1	2	18.2	1	9.1
	IMPROVEMENT	1	100										1	100			
	PATIENT UNCOOPERATIVE	8	100			3	37.5			2	25.0	1	12.5	2	25.0		
	OTHER	1	100								1	100					
	Total	38	100			13	34.2	6	15.8	8	21.1	3	7.9	5	13.2	3	7.9
Placebo	ADVERSE EVENT (*)	8	100			2	25.0	2	25.0	1	12.5	2	25.0			1	12.5
	LOST TO FOLLOW UP	1	100	1	100												
	DETERIORATION	11	100					3	27.3	2	18.2	5	45.5	1	9.1		
	PATIENT UNCOOPERATIVE	6	100			3	50.0	1	16.7	1	16.7	1	16.7				
	Total	26	100	1	3.8	5	19.2	6	23.1	4	15.4	8	30.8	1	3.8	1	3.8
Reboxetine	ADVERSE EVENT (*)	12	100			4	33.3	3	25.0	1	8.3	3	25.0	1	8.3		
	PROTOCOL VIOLATION	1	100					1	100								
	DETERIORATION	5	100			1	20.0	1	20.0	1	20.0	2	40.0				
	PATIENT UNCOOPERATIVE	5	100			1	20.0	1	20.0	1	20.0			2	40.0		
	Total	23	100			6	26.1	6	26.1	3	13.0	5	21.7	3	13.0		

(*) ADVERSE EVENT: to be considered as adverse event or intercurrent medical problems

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 4
PROTOCOL VIOLATION AT ADMISSION

	Imipramine		Placebo		Reboxetine	
	No.	%	No.	%	No.	%
Patients exposed	115	100.00	112	100.00	112	100.00
Age > 65 years					1	0.89
Pregnancy						
Thyroid function tests abnormal*	12	10.43	6	5.36	5	4.46
Thyroid function tests missing	16	13.91	11	9.82	11	9.82
Evidence of Substance Use Disorder						
Associated endocrine disorder						
Not allowed concomitant medication during wash-out	3	2.61	1	0.89	6	5.36
Index episode < 4 weeks	1	0.87	2	1.79		
Index episode > 4 months	4	3.48	2	1.79	3	2.68
Index episode duration: unknown						
Clinical relevant associated pathology						

* > 10% deviation from normal range limits

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Table No.: 5

RANDOMIZATION: ASSIGNED TREATMENT vs RANDOMIZED TREATMENT

Assigned treatment	Randomized treatment			Total
	Imipramine	Placebo	Reboxetine	
Imipramine	89	9	16	115
Reboxetine	19	12	80	112
Placebo	6	91	15	112
Total	114	112	111	339

9550082

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PHARMACIA CNS R8D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 6

COMPLIANCE TO SCHEDULE TIME AS PER PROTOCOL

Assigned treatment: Reboxetine

	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Assessment time	No.	112	106	100	97	92	89	89
	Min	-25	7	13	20	27	34	41
	Max	1	8	16	25	31	42	62
	Median	-4	8	15	22	29	36	43
	95th percentile	1	8	15	23	30	37	44
Laboratory test	No.	110			94			86
	Min	-46			14			35
	Max	4			30			74
	Median	-3			22			43
	95th percentile	1			24			48
E.C.G.	No.	111			96			89
	Min	-45			13			35
	Max	9			29			74
	Median	-4			22			43
	95th percentile	2			25			52

9550082

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PHARMACIA CNS R&D
 REDOMETINE - PROTOCOL 2012A/015
 TABLE No.: 6

COMPLIANCE TO SCHEDULE TIME AS PER PROTOCOL

Assigned treatment: Imipramine

	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Assessment time	No.	115	102	96	88	85	80	77
	Min	-24	6	13	20	26	34	41
	Max	1	14	18	28	35	43	47
	Median	-4	8	15	22	29	36	43
	95th percentile	1	8	16	24	31	38	45
Laboratory test	No.	111			85			75
	Min	-35			16			33
	Max	7			31			57
	Median	-3			22			43
	95th percentile	1			25			48
E.C.G.	No.	115			84			77
	Min	-104			20			36
	Max	5			36			78
	Median	-3			22			43
	95th percentile	1			25			57

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 6

COMPLIANCE TO SCHEDULE TIME AS PER PROTOCOL

Assigned treatment: Placebo

	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Assessment time	No.	112	106	100	96	88	87	86
	Min	-27	7	12	19	26	34	40
	Max	1	9	22	24	36	40	48
	Median	-4	8	15	22	29	36	43
	95th percentile	1	8	15	22	30	37	45
Laboratory test	No.	109			94			81
	Min	-56			15			36
	Max	8			31			66
	Median	-3			22			43
	95th percentile	1			25			48
E.C.G.	No.	111			95			85
	Min	-48			19			29
	Max	8			32			75
	Median	-3			22			43
	95th percentile	2			28			54

9550082

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PHARRACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Table No.: 7

CONCOMITANT DRUGS NOT ALLOWED BY PROTOCOL GROUPED BY ACTIVE PRINCIPLE
 NUMBER OF PATIENTS

Class / Active principle	Assigned treatment	
	Placebo	Imipramine
BDZ long acting	DIAZEPAM	2
	MITRAZEPAM	1
	FLURAZEPAM	1
	LORAZEPAM	1
	Total	4
Neuroleptics	CHLORMEZANONE	1
	Total	1
Antiepileptics	CLONAZEPAM	1
	Total	1

9550082

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Table No.: 8

CONCOMITANT DRUGS NOT ALLOWED BY PROTOCOL GROUPED BY CLASS
NUMBER OF PATIENTS

	Assigned treatment	
	Imipramine	Placebo
At least one	1	5
Antiepileptics	1	
BDZ long acting	1	4
Neuroleptics		1

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Table No.: 9

DEMOGRAPHY BY ASSIGNED TREATMENT - AGE, HEIGHT, HEIGHT

Assigned treatment	Age			Weight			Height			
	Sex		Total	Sex		Total	Sex		Total	
	Female	Male		Female	Male		Female	Male		
Imipramine	No	77	38	115	77	38	115	77	38	115
	Mean	43.57	43.32	43.49	62.96	76.46	67.42	161.58	174.00	165.69
	S.D.	11.38	10.54	11.06	11.88	10.54	13.07	6.61	6.89	8.88
	Min	20.00	22.00	20.00	40.00	55.00	40.00	140.00	158.00	140.00
	Max	62.00	65.00	65.00	99.00	99.00	99.00	179.00	185.00	185.00
	No	54	58	112	53	58	111	54	57	111
Placebo	Mean	45.11	41.67	43.33	63.24	75.52	69.66	161.81	173.39	167.76
	S.D.	12.19	11.06	11.69	11.55	13.72	14.09	4.86	7.00	8.37
	Min	23.00	18.00	18.00	41.00	48.50	41.00	150.00	155.00	150.00
	Max	65.00	63.00	65.00	91.00	133.00	133.00	174.00	193.00	193.00
	No	70	42	112	69	42	111	78	42	112
	Mean	45.43	46.74	45.92	63.83	76.41	68.59	161.20	174.31	166.12
Reboxetine	S.D.	13.54	11.23	12.68	14.45	13.41	15.29	6.58	6.97	9.25
	Min	19.00	23.00	19.00	38.00	61.00	38.00	147.00	154.00	147.00
	Max	72.00	64.00	72.00	116.00	141.00	141.00	176.00	188.00	188.00
	No	201	138	339	199	138	337	201	137	338
	Mean	44.63	43.67	44.24	63.34	76.05	68.54	161.51	173.84	166.51
	S.D.	12.35	11.10	11.85	12.69	12.74	14.15	6.15	6.92	8.86
Total	Min	19.00	18.00	18.00	38.00	48.50	38.00	140.00	154.00	140.00
	Max	72.00	65.00	72.00	116.00	141.00	141.00	179.00	193.00	193.00
	No	201	138	339	199	138	337	201	137	338
	Mean	44.63	43.67	44.24	63.34	76.05	68.54	161.51	173.84	166.51
	S.D.	12.35	11.10	11.85	12.69	12.74	14.15	6.15	6.92	8.86
	Min	19.00	18.00	18.00	38.00	48.50	38.00	140.00	154.00	140.00
Max	72.00	65.00	72.00	116.00	141.00	141.00	179.00	193.00	193.00	

weight and height at screening visit

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Table No.: 10

DEMOGRAPHY BY ASSIGNED TREATMENT - RACE

Assigned treatment / Sex	Race										
	Caucasian			Asian			Other			Total	
	No.	Z	%	No.	Z	%	No.	Z	%		
Imipramine	Female	77	100.00							77	100.00
	Male	37	97.37			1	2.63			38	100.00
	Total	114	99.13			1	0.87			115	100.00
Placebo	Female	52	96.30	2	3.70					54	100.00
	Male	56	96.55			2	3.45			58	100.00
	Total	108	96.43	2	1.79	2	1.79			112	100.00
Reboxetine	Female	69	98.57			1	1.43			70	100.00
	Male	42	100.00							42	100.00
	Total	111	99.11			1	0.89			112	100.00
Total	Female	198	98.51	2	1.00	1	0.50			201	100.00
	Male	135	97.83			3	2.17			138	100.00
	Total	333	98.23	2	0.59	4	1.18			339	100.00

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 11
DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

	Sex													
	Female						Male						Total	
	Imipramine	Placebo	Reboxetine	Total	Imipramine	Placebo	Reboxetine	Total	Imipramine	Placebo	Reboxetine	Total		
Duration of last episode (weeks)	No.	52	43	51	146	24	37	25	86	76	80	232		
	Mean	17.96	17.09	12.94	15.95	14.17	30.00	13.96	20.92	16.76	23.06	17.79		
	STD	22.26	12.44	7.37	15.58	20.05	62.39	10.51	43.03	21.52	43.56	28.97		
	Median	12.00	12.00	12.00	12.00	10.00	12.00	12.00	12.00	12.00	12.00	12.00		
	Min	3	1	4	1	2	3	4	2	2	1	4		
	Max	156	52	39	156	104	364	52	364	156	364	364		
Duration of present episode (weeks)	No.	77	54	70	201	38	58	42	138	115	112	339		
	Mean	8.01	8.21	8.84	8.35	8.28	9.06	8.71	8.74	8.10	8.65	8.51		
	STD	3.93	3.77	3.89	3.87	3.74	4.30	3.65	3.94	3.86	4.05	3.90		
	Median	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00		
	Min	3	3	3	3	3	3	3	3	3	3	3		
	Max	20	16	16	20	16	24	16	24	20	24	24		

9550082

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PHARMACIA CNS RRD

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 12

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

All patients

	Imipramine		Placebo		Reboxetine		Total		
	No	%	No	%	No	%	No	%	
Charact. of present episode	Exacerbation of chronic cond.	9	7.83	12	10.71	11	9.82	32	9.44
	Recurrence of similar prev. cond.	65	56.52	63	56.25	65	58.04	193	56.93
	Different from any prev. cond.	9	7.83	8	7.14	7	6.25	24	7.08
	First occurrence	32	27.83	29	25.89	29	25.89	90	26.55
Total	115	100.00	112	100.00	112	100.00	339	100.00	
Onset of present episode	Acute (< 2 weeks)	16	13.91	9	8.04	16	14.29	41	12.09
	Subacute (>= 2 & < 12 weeks)	82	71.30	76	67.86	64	57.14	222	65.49
	Insidious (>= 3 months)	17	14.78	26	23.21	32	28.57	75	22.12
	Unknown			1	0.89			1	0.29
Total	115	100.00	112	100.00	112	100.00	339	100.00	
Precipit. external stress	Absent	47	40.87	44	39.29	44	39.29	135	39.82
	Probably present	48	41.74	54	48.21	47	41.96	149	43.95
	Definitely present	19	16.52	14	12.50	21	18.75	54	15.93
	Unknown	1	0.87					1	0.29
Total	115	100.00	112	100.00	112	100.00	339	100.00	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 12

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

Sex: Female

	Imipramine		Placebo		Reboxetine		Total	
	No	Z	No	Z	No	Z	No	Z
Charact. of present episode	6	7.79	6	11.11	5	7.14	17	8.46
	45	58.44	35	64.81	45	64.29	125	62.19
	7	9.09	4	7.41	5	7.14	16	7.96
	19	24.68	9	16.67	15	21.43	43	21.39
Total	77	100.00	54	100.00	70	100.00	201	100.00
Onset of present episode	11	14.29	4	7.41	10	14.29	25	12.44
	56	72.73	38	70.37	42	60.00	136	67.66
	10	12.99	11	20.37	18	25.71	39	19.40
			1	1.85			1	0.50
Total	77	100.00	54	100.00	70	100.00	201	100.00
Precipit. external stress	32	41.56	23	42.59	28	40.00	83	41.29
	33	42.86	24	44.44	30	42.86	87	43.28
	12	15.58	7	12.96	12	17.14	31	15.42
	77	100.00	54	100.00	70	100.00	201	100.00

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 12

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

Sex: Male

	Imipramine		Placebo		Reboxetine		Total	
	No	Z	No	Z	No	Z	No	Z
Charact. of present episode	3	7.89	6	10.34	6	14.29	15	10.87
	20	52.63	28	48.28	20	47.62	68	49.28
	2	5.26	4	6.90	2	4.76	8	5.80
	13	34.21	20	34.48	14	33.33	47	34.06
	38	100.00	58	100.00	42	100.00	138	100.00
Onset of present episode	5	13.16	5	8.62	6	14.29	16	11.59
	26	68.42	38	65.52	22	52.38	86	62.32
	7	18.42	15	25.86	14	33.33	36	26.09
	38	100.00	58	100.00	42	100.00	138	100.00
Precipit. external stress	15	39.47	21	36.21	16	38.10	52	37.68
	15	39.47	30	51.72	17	40.48	62	44.93
	7	18.42	7	12.07	9	21.43	23	16.67
	1	2.63					1	0.72
Total	38	100.00	58	100.00	42	100.00	138	100.00

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 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 12.1
 MINI MENTAL STATE - TOTAL SCORE

	Imipramine	Placebo	Reboxetine
No.	115	112	112
Mean	27.90	28.06	27.91
STD	2.12	2.09	1.98
Median	28.00	29.00	28.00
Min	20	20	20
Max	30	30	30

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 13

PREVIOUS ANTIDEPRESSIVE TREATMENT BY ACTIVE PRINCIPLE

	Assigned treatment												Total	
	Placebo			Imipramine			Reboxetine			Total				
	No	z	%	No	z	%	No	z	%	No	z	%		
Screened patient	112	100.0	100.0	115	100.0	100.0	112	100.0	100.0	339	100.0	100.0		
CLOMIPRAMINE	13	11.6	11.6	11	9.6	9.6	14	12.5	12.5	38	11.2	11.2		
FLUOXETINE	9	8.0	8.0	11	9.6	9.6	12	10.7	10.7	32	9.4	9.4		
AMITRIPTYLINE	7	6.3	6.3	3	2.6	2.6	11	9.8	9.8	21	6.2	6.2		
DOSULEPIN	10	8.9	8.9	1	0.9	0.9	5	4.5	4.5	16	4.7	4.7		
TRIMIPRAMINE	6	5.4	5.4	5	4.3	4.3	3	2.7	2.7	14	4.1	4.1		
FLUOXAMINE	4	3.6	3.6	4	3.5	3.5	5	4.5	4.5	13	3.8	3.8		
MIANSERIN	6	5.4	5.4	4	3.5	3.5	2	1.8	1.8	12	3.5	3.5		
LITHIUM	3	2.7	2.7	3	2.6	2.6	2	1.8	1.8	8	2.4	2.4		
IMIPRAMINE	4	3.6	3.6	3	2.6	2.6	1	0.9	0.9	8	2.4	2.4		
DOXEPIN	3	2.7	2.7	2	1.7	1.7	3	2.7	2.7	8	2.4	2.4		
TIANEPTINE	2	1.8	1.8	4	3.5	3.5	2	1.8	1.8	8	2.4	2.4		
MAPROTILINE	1	0.9	0.9	3	2.6	2.6	2	1.8	1.8	6	1.8	1.8		
LOFEPRAMINE	1	0.9	0.9	2	1.7	1.7	2	1.8	1.8	5	1.5	1.5		
TRANILCYPRONINE	2	1.8	1.8	2	1.7	1.7	1	0.9	0.9	5	1.5	1.5		
VILOXAZINE	2	1.8	1.8	1	0.9	0.9	2	1.8	1.8	5	1.5	1.5		
VENLAFAXINE	1	0.9	0.9	2	1.7	1.7	1	0.9	0.9	4	1.2	1.2		
NORTRIPTYLINE				2	1.7	1.7	1	0.9	0.9	3	0.9	0.9		
AMINEPTINE	1	0.9	0.9				2	1.8	1.8	3	0.9	0.9		
DESIPRAMINE	2	1.8	1.8	1	0.9	0.9				3	0.9	0.9		
MEDIFOXAMINE	1	0.9	0.9				2	1.8	1.8	3	0.9	0.9		
TRAZODONE	1	0.9	0.9	1	0.9	0.9				2	0.6	0.6		
MOCLOBEMIDE				2	1.7	1.7				2	0.6	0.6		

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 13

PREVIOUS ANTIDEPRESSIVE TREATMENT BY ACTIVE PRINCIPLE

	Assigned treatment										Total	
	Placebo		Imipramine		Reboxetine		Reboxetine		Total			
	No	%	No	%	No	%	No	%	No	%	No	%
DIBENZEPIN	1	0.9	1	0.9					2	0.6		
PHENELZINE	1	0.9							1	0.3		
PAROXETINE	1	0.9							1	0.3		
AMOXAPINE			1	0.9					1	0.3		
TOLIXATONE			1	0.9					1	0.3		
METAPRAMINE			1	0.9					1	0.3		
QUINUPRAMINE			1	0.9					1	0.3		

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 14

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS OF SCREENED PATIENTS BY SEX AND ASSIGNED TREATMENT

1108

Previous diseases	Female						Male						Total												
	Imipramine		Reboxetine		Placebo		Total		Imipramine		Reboxetine		Placebo		Total		Imipramine		Reboxetine		Placebo		Total		
	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	
Screened patients	77	100	70	100	54	100	201	100	38	100	42	100	58	100	138	100	112	100	112	100	112	100	339	100	
HYPERTENSION NOS	4	5.2	3	4.3	3	5.6	10	5.0	1	2.6	2	4.8	1	1.7	4	2.9	5	4.3	5	4.5	4	3.6	14	4.1	
URIN TRACT INFECTION NOS	2	2.6	4	5.7			6	3.0					1	1.7	1	0.7	2	1.7	4	3.6	1	0.9	7	2.1	
DIABETES MELLITUS UNCOMP	2	2.6					2	1.0			3	7.1			3	2.2	2	1.7	3	2.7			5	1.5	
MALIGN NEOPL BREAST NOS	2	2.6	1	1.4			3	1.5									2	1.7	1	0.9			3	0.9	
OTHER GU NEOPLASH NOS	2	2.6	1	1.4	2	3.7	5	2.5									2	1.7	1	0.9	2	1.8	5	1.5	
GOITER NOS	2	2.6					2	1.0	1	2.6					1	0.7	3	2.6					3	0.9	
OBESITY	2	2.6	1	1.4	1	1.9	4	2.0			1	2.4	1	1.7	2	1.4	2	1.7	2	1.8	2	1.8	6	1.8	
PNEUMONIA, ORGANISM NOS	2	2.6					2	1.0					1	1.7	1	0.7	2	1.7			1	0.9	3	0.9	
APPENDICITIS NOS	2	2.6					2	1.0									2	1.7					2	0.6	
HEADACHE	2	2.6					2	1.0									2	1.7					2	0.6	
TACHYCARDIA NOS	2	2.6					2	1.0									2	1.7					2	0.6	
ASTHMA NOS					2	3.7	2	1.0														2	1.8	2	0.6
ALCOHOL DEPENDENCE SYNDR	1	1.3	2	2.9			3	1.5	2	5.3					2	1.4	3	2.6	2	1.8			5	1.5	
CIRCULATORY DISEASE NOS			2	2.9	1	1.9	3	1.5	1	2.6					1	0.7	1	0.9	2	1.8	1	0.9	4	1.2	
PURE HYPERCHOLESTEROLEM	1	1.3			1	1.9	2	1.0	1	2.6			2	3.4	3	2.2	2	1.7			3	2.7	5	1.5	
DIARRHEA OF INFECT ORIG	1	1.3					1	0.5									1	0.9					1	0.3	
PULMONARY TB NOS	1	1.3					1	0.5									1	0.9					1	0.3	
THYROIDITIS NOS	1	1.3					1	0.5									1	0.9					1	0.3	
HYPOTHYROIDISM NOS	1	1.3	1	1.4			2	1.0									1	0.9	1	0.9			2	0.6	
HYPERLIPIDEMIA NEC/NOS	1	1.3	1	1.4			2	1.0	1	2.6			1	1.7	2	1.4	2	1.7	1	0.9	1	0.9	4	1.2	
HYPOPOTASSEMIA	1	1.3					1	0.5									1	0.9					1	0.3	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 14

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS OF SCREENED PATIENTS BY SEX AND ASSIGNED TREATMENT

149

Previous diseases	Female						Male						Total										
	Imipramine		Reboxetine		Placebo		Imipramine		Reboxetine		Placebo		Imipramine		Reboxetine		Placebo		Total				
	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.			
CHR ISCHEMIC HRT DIS NEC	1	1.3					1	0.5								1	0.9				1	0.3	
PREMATURE BEATS	1	1.3					1	0.5								1	0.9				1	0.3	
CARDIAC DYSRHYTHMIAS NEC	1	1.3					1	0.5								1	0.9				1	0.3	
THROMBOPHLEBITIS LEG NOS	1	1.3					1	0.5								1	0.9				1	0.3	
HYPOTENSION NOS	1	1.3			1	1.9	2	1.0								1	0.9			1	0.9	2	0.6
FLU W RESP MANIFEST NEC	1	1.3					1	0.5								1	0.9				1	0.3	
BRONCHITIS NOS	1	1.3					1	0.5								1	0.9				1	0.3	
DUODENAL ULCER NOS	1	1.3					1	0.5				1	1.7			1	0.9			1	0.9	2	0.6
PEPTIC ULCER NOS	1	1.3					1	0.5								1	0.9				1	0.3	
GASTRITIS/DUODENITIS NOS	1	1.3		1	1.4		2	1.0								1	0.9		1	0.9	2	0.6	
ACUTE APPENDICITIS NOS	1	1.3				1	1.9	2	1.0							1	0.9			1	0.9	2	0.6
ALCOHOL LIVER DAMAGE NOS	1	1.3					1	0.5								1	0.9				1	0.3	
CALCULUS OF KIDNEY	1	1.3					1	0.5								1	0.9				1	0.3	
INFERTILITY-TUBAL ORIGIN	1	1.3					1	0.5								1	0.9				1	0.3	
CERVICAL SPONDYLOSIS	1	1.3					1	0.5								1	0.9				1	0.3	
PANNICULITIS OF NECK	1	1.3					1	0.5								1	0.9				1	0.3	
BACKACHE NOS	1	1.3					1	0.5				1	2.4			1	0.9		1	0.9	2	0.6	
CONGENITAL ANOMALIES NEC	1	1.3					1	0.5								1	0.9				1	0.3	
PALPITATIONS	1	1.3					1	0.5								1	0.9				1	0.3	
FX TARSAL/METATARS NEC-CL	1	1.3					1	0.5								1	0.9				1	0.3	
FRACTURE NOS	1	1.3					1	0.5								1	0.9				1	0.3	
ALLERGY, UNSPECIFIED	1	1.3					1	0.5								1	0.9				1	0.3	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 14

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS OF SCREENED PATIENTS BY SEX AND ASSIGNED TREATMENT

120

Previous diseases	Female						Male						Total							
	Imipramine			Placebo			Imipramine			Placebo			Imipramine			Placebo				
	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.		
																			No	Z on Pt.
HEPATITIS A N/O COMA			1	1.9	1	0.5											1	0.9	1	0.3
BENIGN NEOPLASM SKIN NOS			1	1.9	1	0.5											1	0.9	1	0.3
BENIGN NEOPLASM BREAST			1	1.9	1	0.5											1	0.9	1	0.3
BENIGN NEO UTERUS NOS			1	1.9	1	0.5											1	0.9	1	0.3
EMOTIONAL DIS CHILD NOS			1	1.9	1	0.5											1	0.9	1	0.3
MIGRAINE NOS			1	1.9	1	0.5											1	0.9	1	0.3
VARICOSE VEIN OF LEG NOS			1	1.9	1	0.5						1	1.7				2	1.8	2	0.6
DIAPHRAGMATIC HERNIA			1	1.9	1	0.5											1	0.9	1	0.3
HEPATITIS NOS			1	1.9	1	0.5											1	0.9	1	0.3
CHOLELITH W CHOLECYSTEC			1	1.9	1	0.5											1	0.9	1	0.3
INTEST MALABSORPTION NEC			1	1.9	1	0.5											1	0.9	1	0.3
CERVICITIS			1	1.9	1	0.5											1	0.9	1	0.3
METORRHAGIA			1	1.9	1	0.5											1	0.9	1	0.3
PARAPROXIFEN			1	1.9	1	0.5											1	0.9	1	0.3
SPONDYLOSIS NOS			1	1.9	1	0.5			1	2.6							1	0.9	1	0.3
CERVICALGIA			1	1.9	1	0.5											1	0.9	1	0.3
SCIATICA			1	1.9	1	0.5											1	0.9	1	0.3
OSTEITIS DEFORMANS NOS			1	1.9	1	0.5											1	0.9	1	0.3
OSTEOPOROSIS			1	1.4	1	1.0											1	0.9	1	0.3
BONE/CARTIL DIS NEC/NOS			1	1.4	1	1.0											1	0.9	1	0.3
FLAT FOOT			1	1.9	1	0.5											1	0.9	1	0.3
OTHER SKIN ANOMALIES			1	1.9	1	0.5											1	0.9	1	0.3

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012/015
TABLE No.: 14
MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS OF SCREENED PATIENTS BY SEX AND ASSIGNED TREATMENT

121

Previous diseases	Female						Male						Total												
	Imipramine			Reboxetine			Placebo			Total			Imipramine			Reboxetine			Placebo			Total			
	Z on Pt.	No		Z on Pt.	No		Z on Pt.	No		Z on Pt.	No		Z on Pt.	No		Z on Pt.	No		Z on Pt.	No		Z on Pt.	No		
ABN LIVER FUNCTION STUDY							1	1.9	1	0.5															
BRAIN INJURY NEC							1	1.9	1	0.5															
SPINAL CORD INJURY NOS							1	1.9	1	0.5															
TRUNK INJURY NOS							1	1.9	1	0.5															
SARCIDOSIS							1	1.4																	
DIS IRON METABOLISM							1	1.4																	
ANEMIA NOS							1	1.4																	
STAMMERING STUTTERING							1	1.4																	
ANOREXIA NERVOSA							1	1.4																	
HEARING LOSS NOS							1	1.4																	
ALLERGIC RHINITIS NOS							1	1.4																	
DIVERTICULA OF COLON							1	1.4																	
PREMENSTRUAL TENSION							1	1.4																	
UNSPECIFIED ABORTION							1	1.4																	
PRURITIC DISORDER NOS							1	1.4																	
DISC DISPLACEMENT NOS							1	1.4																	
MYALGIA AND MYOSITIS NOS							1	1.4																	
PAIN IN LIMB							1	1.4																	
CHONDRODYSPLASIA							1	1.4																	
ABN URINE FINDINGS NEC							1	1.4																	
FX BIMALLEOLAR-CLOSED							1	1.4																	
DIGESTIVE NEOPLASIA NOS																									

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No. : 14

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS OF SCREENED PATIENTS BY SEX AND ASSIGNED TREATMENT

Previous diseases	Female						Male						Total												
	Imipramine			Reboxetine			Placebo			Total			Imipramine			Reboxetine			Placebo			Total			
	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	
																									No
PURE HYPERGLYCEMIDEMIA																									
AC INFECT POLYNEURITIS																									
AC PERICARDITIS NEC/NOS																									
STOMACH ULCER NOS																									
INGUIN HERNIA N OBSTRUCT																									
OTHER PSORIASIS																									
ARTHROPATHY NOS																									
VERTEBRAL FX NOS-CLOSED																									
LOWER LEG INJURY NOS																									
ACUTE POLIOMYELITIS NOS																									
ACUTE BRONCHITIS																									
OBSTRUCT CHR BRONCHITIS																									
PNEUMOTHORAX																									
ANKYLOSING SPONDYLITIS																									
THORAC/LUMB DISC DISPLAC																									
ABN BLOOD CHEMISTRY NEC																									
RETINAL DETACHMENT NOS																									
SENILE CATARACT																									
ATRIAL FIBRILL/FLUTTER																									
ARTERITIS NOS																									
HEMORRHOIDS NOS																									
CHRONIC LIVER DIS NEC																									

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 15
MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS OF SCREENED PATIENTS BY BODY SYSTEM, SEX AND ASSIGNED TREATMENT

Previous diseases (body system)	Female						Male						Total											
	Imipramine		Reboxetine		Placebo		Total		Imipramine		Reboxetine		Placebo		Total		Imipramine		Reboxetine		Placebo		Total	
	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.	No	Z on Pt.
Screened Patients	77	100	70	100	54	100	201	100	38	100	42	100	58	100	133	100	115	100	112	100	112	100	339	100
CIRCULATORY SYSTEM	7	9.1	5	7.1	5	9.3	17	8.5	3	7.9	5	11.9	2	3.4	10	7.2	10	8.7	10	8.9	7	6.3	27	8.0
GENITOURINARY SYSTEM	4	5.2	5	7.1	2	3.7	11	5.5					1	1.7	1	0.7	4	3.5	5	4.5	3	2.7	12	3.5
ENDOCR., NUTRIT. AND METAB. DISEASES	9	11.7	4	5.7	2	3.7	15	7.5	4	10.5	4	9.5	4	6.9	12	8.7	13	11.3	8	7.1	6	5.4	27	8.0
NEOPLASM	3	3.9	1	1.4	5	9.3	9	4.5	1	2.6					1	0.7	4	3.5	1	0.9	5	4.5	10	2.9
RESPIRATORY SYSTEM	3	3.9	1	1.4	2	3.7	6	3.0					3	5.2	3	2.2	3	2.6	1	0.9	5	4.5	9	2.7
DIGESTIVE SYSTEM	5	6.5	2	2.9	5	9.3	12	6.0	2	5.3	2	4.8	1	1.7	5	3.6	7	6.1	4	3.6	6	5.4	17	5.0
SYMPTOMS, SIGNS AND ILL DEFINED CONDITIONS	4	5.2	1	1.4	1	1.9	6	3.0					2	3.4	2	1.4	4	3.5	1	0.9	3	2.7	8	2.4
MENTAL DISORDERS	1	1.3	3	4.3	1	1.9	5	2.5	2	5.3					2	1.4	3	2.6	3	2.7	1	0.9	7	2.1
INFECTIOUS AND PARASITIC DISEASE	2	2.6	1	1.4	1	1.9	4	2.0			1	2.4	1	1.7	2	1.4	2	1.7	2	1.8	2	1.8	6	1.8
MUSCULOSKELETAL SYS. AND CONNECTIVE TISSUE	3	3.9	4	5.7	6	11.1	13	6.5	3	7.9	2	4.8	2	3.4	7	5.1	6	5.2	6	5.4	8	7.1	20	5.9
CONGENITAL ANOMALIES	1	1.3	1	1.4	1	1.9	3	1.5									1	0.9	1	0.9	1	0.9	3	0.9
INJURY AND POISONING	3	3.9	1	1.4	3	5.6	7	3.5	2	5.3					2	1.4	5	4.3	1	0.9	3	2.7	9	2.7
NERVOUS SYSTEM AND SENSE ORGANS			1	1.4	1	1.9	2	1.0	1	2.6	1	2.4			2	1.4	1	0.9	2	1.8	1	0.9	4	1.2
SKIN AND SUBCUTANEOUS TISSUE			1	1.4	1	1.9	2	1.0	1	2.6					1	0.7	1	0.9	1	0.9	1	0.9	3	0.9
BLOOD AND BLOOD-FORMING ORGANS			1	1.4			1	0.5											1	0.9			1	0.3
PREGNANCY, CHILDBIRTH AND Puerperium			1	1.4			1	0.5											1	0.9			1	0.3

PHARMACIA CNS R 9550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 16

EXPERIMENTAL TREATMENT: NUMBER OF PATIENTS ACCORDING TO DOSE TAKEN ON EACH DAY AND ON DAYS OF ASSESSMENT DURING THERAPY BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

days of treatment	Dose (mg/day)												Total	
	0		4		8		10		12		18			
	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Day 0	1		20	17.9	92	82.1							112	100
1					112	100							112	100
2			2	1.8	109	98.2							111	100
3	1	0.9	1	0.9	108	98.2							110	100
4					108	100							108	100
5					107	100							107	100
6			2	2.0	98	98.0							100	100
7					1	100							1	100
8					105	99.1			1	0.9			106	100
Day 7					106	100							106	100
1					106	100							106	100
2			2	1.9	103	97.2			1	0.9			106	100
3					104	98.1			1	0.9			106	100
4	1	0.9	2	1.9	101	97.1							104	100
5	1	1.0	1	1.0	97	98.0							99	100
6	1	1.0	2	50.0	2	50.0							4	100
7			2	2.0	98	98.0							100	100
8			1	1.0	99	99.0							100	100
Day 14			1	1.0	99	99.0							100	100
1			1	1.0	99	99.0							100	100
2			1	1.0	99	99.0							100	100
3			1	1.0	99	99.0							100	100
4			1	1.0	99	99.0							100	100
5			1	1.0	99	99.0							100	100
6					99	100							99	100
7					96	100							96	100
8			2	25.0	6	75.0							8	100
9					1	100							1	100
Day 21					77	79.4	18	18.6			2	2.1	97	100
1					77	79.4	18	18.6			2	2.1	97	100
2			3	3.1	74	76.3	18	18.6			2	2.1	97	100
3			2	2.1	76	78.4	17	17.5			2	2.1	97	100
4			1	1.0	74	77.1	19	19.8			2	2.1	96	100
5			2	2.2	74	78.7	18	19.1			2	2.1	94	100
6			2	2.2	71	77.2	17	18.5			2	2.2	92	100
7	1	14.3	1	14.3	5	71.4							7	100
8					1	100							1	100
9					67	72.8	21	22.8			3	3.3	92	100
Day 28					67	72.8	21	22.8			3	3.3	92	100
1	1	1.1			66	71.7	22	23.9			2	2.2	92	100
2	1	1.1	1	1.1	66	71.7	22	23.9			2	2.2	92	100
3	1	1.1			67	72.8	22	23.9			2	2.2	92	100
4	2	2.2			67	72.8	22	23.9			2	2.2	92	100
5	1	1.1			66	72.5	21	23.1			2	2.2	91	100
6	1	1.1	1	1.1	64	72.7	20	22.7			2	2.3	88	100
7	1	1.1			1	50.0							2	100
8			1	1.1	64	71.9	22	24.7			2	2.2	89	100
Day 35					64	71.9	23	25.8			2	2.2	89	100
1					64	71.9	23	25.8			2	2.2	89	100
2					64	71.9	23	25.8			2	2.2	89	100
3			1	1.1	64	71.9	22	24.7			2	2.2	89	100
4			1	1.1	64	71.9	22	24.7			2	2.2	89	100
5			1	1.1	64	72.7	21	23.9			2	2.3	88	100
6			3	3.5	60	69.8	21	24.4			2	2.3	86	100
7			11	64.7	4	23.5	2	11.8					17	100
8			2	66.7	1	33.3							3	100
9														

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PHARMACIA CNS R5550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 16

EXPERIMENTAL TREATMENT: NUMBER OF PATIENTS ACCORDING TO DOSE TAKEN ON EACH DAY AND ON DAYS OF ASSESSMENT DURING THERAPY BY ASSIGNED TREATMENT

Assigned treatment: Imipramine

days of treatment	Dose (mg/day)														Total	
	0		50		100		150		200		300		350			
	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Day 0	3	2.6	17	14.8	95	82.6									115	100
1	3	2.6	1	0.9	111	96.5									115	100
2	2	1.8			111	97.4			1	0.9					114	100
3	3	2.7					109	96.5			1	0.9			113	100
4	3	2.7					109	97.3							112	100
5	4	3.6	1	0.9			107	95.5							112	100
6	3	2.9	4	3.9	2	1.9	94	91.3							103	100
7	2	15.4	4	30.8			7	53.8							13	100
8	1	100													1	100
9	2	2.0	1	1.0			99	97.1							102	100
Day 7	2	2.0					99	98.0							101	100
1	2	2.0	2	2.0			96	96.0							100	100
2	2	2.1	2	2.1			93	95.9							97	100
3	1	1.0	1	1.0			95	97.9							97	100
4	1	1.0	1	1.0	1	1.0	94	96.9							97	100
5	1	1.1	1	1.1			91	97.8							93	100
6	1	14.3	1	14.3			5	71.4							7	100
7	2	2.1	1	1.1			92	96.8							95	100
8	2	2.1	2	2.1			91	95.8							95	100
9	2	2.1	1	1.1	1	1.1	91	95.8							95	100
Day 14	1	1.1	1	1.1			92	97.9							94	100
1	1	1.1	3	3.2			90	95.7							94	100
2	1	1.1	2	2.2			90	96.8							93	100
3	1	1.1	2	2.3			85	96.6							88	100
4	1	100					4	100							4	100
5	1	1.1	1	1.1	3	3.4	71	80.7	11	12.5			2	2.3	88	100
6	2	2.3	2	2.3	3	3.4	68	77.3	15	17.0			2	2.3	88	100
7	1	1.2	1	1.2	1	1.1	67	77.0	15	17.2			2	2.3	87	100
8	1	1.2	1	1.2	1	1.2	68	79.1	15	17.4			2	2.3	86	100
9	1	1.2	1	1.2	1	1.2	66	77.6	15	17.6			2	2.4	85	100
Day 21	1	1.2	2	2.4	2	2.4	66	77.6	14	16.5			2	2.4	85	100
1	3	3.8	2	2.5	60	75.0	13	16.2	2	2.5			2	2.5	80	100
2	1	20.0	1	20.0	1	20.0	1	20.0	2	40.0					5	100
3	1	1.2	1	1.2	68	80.0	14	16.5			2	2.4			85	100
4	1	1.2	1	1.2	66	77.6	16	18.8			2	2.4			85	100
5	1	1.2	1	1.2	65	76.5	16	18.8			2	2.4			85	100
6	1	1.2	1	1.2	64	76.2	16	19.0			2	2.4			84	100
7	2	2.4	2	2.4	64	76.2	16	19.0			2	2.4			84	100
8	2	2.4	2	2.4	64	76.2	16	19.0			2	2.4			84	100
9	1	11.1	1	11.1	64	76.2	15	17.9			2	2.4			84	100
Day 28	1	11.1	1	11.1	4	44.4	3	33.3							9	100
1	1	100			1	100									1	100
2	2	2.5			60	75.0	16	20.0			2	2.5			80	100
3	1	1.2			61	76.3	16	20.0			2	2.5			80	100
4	1	1.2			61	76.3	16	20.0			2	2.5			80	100
5	2	2.5	1	1.2	60	75.0	15	18.8			2	2.5			80	100
6	1	1.3			59	75.6	16	20.5			2	2.6			78	100
7	1	1.3			59	75.6	16	20.5			2	2.6			78	100
8	3	4.0	1	1.3	59	75.6	16	20.5			2	2.7			75	100
9	5	38.5	2	15.4	6	46.2	14	18.7							13	100
Day 35	2	100													2	100

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PHARMACIA CNS 89550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 16

EXPERIMENTAL TREATMENT: NUMBER OF PATIENTS ACCORDING TO CAPSULES TAKEN ON EACH DAY AND ON DAYS OF ASSESSMENT DURING THERAPY BY ASSIGNED TREATMENT

Assigned treatment: Placebo

days of treatment	Daily caps										Total	
	0		1		2		3		4			
	No	%	No	%	No	%	No	%	No	%	No	%
Day 0	1	0.9	22	19.6	89	79.5					112	100
2			1	0.9	109	99.1					110	100
3					109	100					109	100
4			1	0.9	108	99.1					109	100
5			1	0.9	107	99.1					108	100
6					107	99.1			1	0.9	108	100
7			1	1.0	100	98.0	1	1.0			102	100
8			1	12.5	7	87.5					8	100
Day 7	1	0.9	1	0.9	103	97.2	1	0.9			106	100
2			1	0.9	105	99.1					106	100
3			1	1.0	104	99.0					105	100
4					104	100					104	100
5					103	100					103	100
6					102	100					102	100
7			2	2.0	97	98.0					99	100
8					9	100					9	100
Day 14	1	1.0	1	1.0	98	98.0					100	100
2	1	1.0	1	1.0	98	98.0					100	100
3	1	1.0	1	1.0	98	98.0					100	100
4	1	1.0	2	2.0	97	97.0					100	100
5	1	1.0	3	3.0	96	96.0					100	100
6	1	1.0	2	2.0	96	97.0					99	100
7			5	5.2	91	94.8					96	100
8			2	40.0	3	60.0					5	100
9			1	100							1	100
Day 21			2	2.1	91	94.8			3	3.1	96	100
2					92	96.8			3	3.2	95	100
3					92	96.8			3	3.2	95	100
4					91	96.8			3	3.2	94	100
5			1	1.1	90	95.7			3	3.2	94	100
6					90	96.8			3	3.2	93	100
7			2	2.2	86	94.5			3	3.3	91	100
8			1	25.0	3	75.0					4	100
9			2	100							2	100
Day 28			1	1.1	85	96.6			2	2.3	88	100
2					86	97.7			2	2.3	88	100
3			1	1.1	85	96.6			2	2.3	88	100
4					86	97.7			2	2.3	88	100
5			1	1.1	85	96.6			2	2.3	88	100
6					86	97.7			2	2.3	88	100
7					83	97.6			2	2.4	85	100
8			1	16.7	5	83.3					6	100
Day 35					85	97.7			2	2.3	87	100
1	1	1.1			84	96.6			2	2.3	87	100
2					85	97.7			2	2.3	87	100
3					85	97.7			2	2.3	87	100
4					85	97.7			2	2.3	87	100
5					84	97.7			2	2.3	86	100
6			1	1.2	83	96.5			2	2.3	86	100
7			4	4.7	79	92.9			2	2.4	85	100
8			13	61.9	8	38.1					21	100
9			2	100							2	100

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/015

TABLE No.: 16.1

EXPERIMENTAL TREATMENT: NUMBER OF PATIENTS WHO SWITCHED FROM LOW TO HIGH DOSE BY ASSIGNED TREATMENT

	Total	visit of first change in dose					
		No	Z	Day 0	Day 21	Day 28	Day 35
Imipramine	always low dose	93	80.87	93			
	at least one high dose	22	19.13	1	18	2	1
	Total	115	100.00	94	18	2	1
Placebo	always low dose	67	60.36	67			
	at least one high dose	44	39.64		39	4	1
	Total	111	100.00	67	39	4	1
Reboxetine	always low dose	86	76.79	86			
	at least one high dose	26	23.21		21	4	1
	Total	112	100.00	86	21	4	1

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 17

EXPERIMENTAL TREATMENT: DISTRIBUTION OF PATIENTS ACCORDING TO CAPSULES TAKEN BY ASSIGNED TREATMENT

	Compliance												Total	
	< 80 %		80 - 89 %		90 - 95 %		95 - 99 %		100 %		Total		No	%
	No	%	No	%	No	%	No	%	No	%	No	%		
Imipramine	3	2.6	2	1.7	15	13.0	14	12.2	81	70.4	115	100.0		
Placebo	2	1.8	1	0.9	7	6.3	18	16.1	84	75.0	112	100.0		
Reboxetine			5	4.5	5	4.5	25	22.3	77	68.8	112	100.0		
Total	5	1.5	8	2.4	27	8.0	57	16.8	242	71.4	339	100.0		

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 18

CONCOMITANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CONCOMITANT MEDICATION BY ASSIGNED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION

Concomitant drugs	Before treatment				During treatment				Total			
	Imipramine		Reboxetine		Imipramine		Reboxetine		Imipramine		Reboxetine	
	No.	No.	No.	No.	No.	No.	No.	No.	No.	No.	No.	
CHLORAL HYDRATE	20	20	18	10	9	8	30	29	26			
TEMAZEPAN	2	3	3	3	4	5	5	7	8			
PARACETANOL	1			1	6	5	2	6	5			
ACETYSALICYLIC ACID	2			3	4		5	4				
LACTULOSE	1			3		1	4		1			
HEPTAMINOL	1	1	1			2	1	1	3			
MAALOX				3	1		3	1				
SENA	1			1	1	1	2	1	1			
AMOXICILLIN					2	2		2	2			
EUGYNON		1		1		1	1	1	1			
METOCLOPRAMIDE						3			3			
ANETROLE				1	1	1	1	1	1			
THEOPHYLLINE		2							2			
DIAZEPAN					2			2				
DIHYDROERGOTAMINE				1		1	1	1	1			
PROPRANOLOL	2											
POTASSIUM			1	1	1			1	1			
ESTRADIOL	1	1						1	1			
IBUPROFEN	1		1					1	1			
SALBUTANOL	1					1		1	1			
NAFTIDROFURYL		1	1						1	1		
NIFEDIPINE		1				1		1	1			

130

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 18

CONCOMITANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CONCOMITANT MEDICATION BY ASSIGNED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION

Concomitant drugs	Before treatment				During treatment				Total			
	Inipramine		Reboxetine		Inipramine		Reboxetine		Placebo		Reboxetine	
	No.	No.	No.	No.	No.	No.	No.	No.	No.	No.	No.	
CALCIOTONIN		1	1								1	1
CAPTOPRIL		2									2	
RANITIDINE		1		1					1		1	
AUGMENTIN						2						2
ENALAPRIL	2								2			
METHYLDOPA	1								1			
ANOVLAR			1									1
BENZYLPENICILLIN					1							1
METRONIDAZOLE					1							1
COLCHICINE						1						1
DIGOXIN						1						1
DIMENHYDRINATE								1				1
ERYTHROMYCIN	1											1
ETHINYLESTRADIOL				1								1
ISPAGHULA						1						1
INSULIN	1											1
FUROSEMIDE						1						1
HYLANTA								1				1
LEVONEPROMAZINE								1				1
NORETHISTERONE	1											1
IMMUNOGLOBULIN HUMAN ANTI-TETANUS								1				1
SULFAMETHIZOLE									1			1

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 18

CONCOMITANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CONCOMITANT MEDICATION BY ASSIGNED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION

Concomitant drugs	Before treatment				During treatment				Total			
	Imipramine		Reboxetine		Imipramine		Reboxetine		Placebo		Reboxetine	
	No.	No.	No.	No.	No.	No.	No.	No.	No.	No.	No.	
TETANUS TOXOID				1							1	
CHLORMEZANONE					1							1
DOXYCYCLINE					1							1
ALKA-SELTZER							1					1
HYDROXYZINE						1						1
CALCIUM GLUCONATE			1									1
CARBACHOL							1					1
DIETHYLSTILBESTROL	1											1
DYDROGESTERONE			1									1
LEVOTHYROXINE	1											1
ESTROGENS CONJUGATED	1											1
PSEUDOEPHEDRINE							1					1
DYAZIDE							1					1
HISTAMINE										1		1
IODINE	1											1
ACETYLCYSTEINE										1		1
ISOSORBIDE DINITRATE	1											1
ETILEFRINE								1				1
AGAROL	1											1
HEDROXYPROGESTERONE	1											1
MULTIVITAMINS												1
TIENONIUM									1			1

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 18

CONCOMITANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CONCOMITANT MEDICATION BY ASSIGNED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION

Concomitant drugs	Before treatment				During treatment				Total			
	Imipramine		Reboxetine		Imipramine		Reboxetine		Imipramine		Reboxetine	
	No.	No.	No.	No.	No.	No.	No.	No.	No.	No.	No.	
ARGININE					1						1	
HYDROXYCARRANIDE	1										1	
MEBEVERINE							1					1
GLIBENCLANIDE			1									1
TRIMETHOPRIM			1									1
DINETICONE							1					1
NORDESTREL			1									1
PHENBARBITAL SALT WITH QUINIDINE	1									1		
NEUROBION FOR INJECTION				1								1
FERROGRAD C						1						1
CLOTRIMAZOLE	1											1
BECLOMETASONE			1									1
APOREX							1					1
NIFLUMIC ACID								1				1
KAO LIN								1				1
GAVISON			1									1
FLUCLOXACILLIN					1							1
FLURAZEPAM					1							1
NAPROXEN							1					1
CITROSAN									1			1
LORAZEPAM							1					1
CLONAZEPAM						1						1

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 1B
 CONCOMITANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CONCOMITANT MEDICATION
 BY ASSIGNED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION

Concomitant drugs	Before treatment				During treatment				Total				
	Imipramine		Reboxetine		Imipramine		Reboxetine		Imipramine		Reboxetine		
	No.	Placebo	No.	Placebo	No.	Placebo	No.	Placebo	No.	Placebo	No.	Placebo	
MICROLAX													
CALCIUM LACTATE		1										1	
KETOPROFEN				1									1
LOPERAMIDE							1						1
URAL													1
ACEBUTOLOL													1
BISTADESTAL					1								1
GLICLAZIDE	1												1
ATENOLOL	1												1
CEFUROXIME							1						1
NIFUROKAZIDE													1
TRASITENSIN													1
SUGUAN													1
DILTIAZEN		1											1
DOMPERIDONE													1
FENOFIBRATE		1											1
NICARDIPINE		1											1
NORFLOXACIN													1
TRITOQUALINE													1
CAPOZIDE													1
CYANEMAZINE													1
CIPROFIBRATE													1

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 18

CONCOMITANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CONCOMITANT MEDICATION BY ASSIGNED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION

Concomitant drugs	Before treatment				During treatment				Total	
	Inipramine		Reboxetine		Inipramine		Reboxetine		Placebo	Reboxetine
	No.	No.	No.	No.	No.	No.	No.	No.	No.	
HEPTAMINOL ADENOSINE PHOSPHATE		1								1
QUINAPRIL		1								1
FUMARIA EXTRACT			1				1			
AGAR							1			1
DEXFENFLURAMINE							1			1
EUPHYTOSE							1			1
GELATIN							1			1
NU-LAX	1								1	
ETHINYL ESTRADIOL N/MORGESTREL							1			1
DEFIBROTIDE							1			1
AMLODIPINE							1			1

135

9550082

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 19
 HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON TOTAL SCORE ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Mean	27.21	26.95	22.41	18.90	14.95	12.47	11.13			
	Median	26	23	18	13	12	9	9			
	STD	5.10	4.67	7.12	8.35	6.36	6.36	6.65			
	Min	22	19	2	0	0	0	0			
	Max	51	51	52	58	28	28	28			
	Mean diff. vs day0 (*)		4.52	8.24	12.29	14.60	16.07	17.70			
Placebo	No	111	111	103	100	93	87	87			
	Mean	27.37	27.12	23.96	18.10	15.90	14.10	13.08			
	Median	26	26	24	17	14	14	11			
	STD	5.15	5.30	6.51	7.75	8.75	7.78	8.06			
	Min	22	20	9	6	2	1	1			
	Max	54	54	53	39	43	34	35			
	Mean diff. vs day0 (*)		3.15	5.30	8.86	11.17	13.00	13.95			
Reboxetine	No	110	110	105	98	97	90	89			
	Mean	27.73	27.53	23.55	16.61	14.46	12.07	11.26			
	Median	26	26	24	19	14	11	10			
	STD	5.21	5.07	6.51	7.87	8.09	7.73	7.55			
	Min	22	22	6	0	0	0	0			
	Max	48	49	45	43	39	38	38			
	Mean diff. vs day0 (*)		3.97	7.68	11.15	13.22	15.72	16.62			

Mean (*): mean of differences vs day0

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 20

FACTORIZATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH FACTOR ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Factor: ANXIETY/SOMATIZATION

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	1.33	1.17	1.00	0.83	0.67	0.50	0.50			
	Min	0.50	0.00	0.00	0.00	0.00	0.00	0.00			
	Max	2.33	2.33	2.50	2.67	1.67	1.67	2.00			
	Median diff. vs day0 (*)		0.17	0.33	0.50	0.67	0.67	0.83			
Placebo	No	111	111	103	100	95	87	87			
	Median	1.33	1.33	1.17	0.83	0.83	0.67	0.67			
	Min	0.67	0.33	0.17	0.00	0.00	0.00	0.00			
	Max	3.00	3.00	3.00	2.50	2.17	2.00	2.00			
	Median diff. vs day0 (*)		0.00	0.17	0.42	0.50	0.67	0.67			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	1.33	1.17	1.00	0.83	0.67	0.67	0.50			
	Min	0.83	0.67	0.00	0.00	0.00	0.00	0.00			
	Max	2.83	2.83	2.33	1.83	1.67	1.83	1.83			
	Median diff. vs day0 (*)		0.17	0.33	0.50	0.67	0.67	0.67			

Median (*): median of differences vs day0

9550082

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 20

FACTORIZATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH FACTOR ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Factor: COGNITIVE DISTURBANCE

Assigned treatment	Screen	Visit													
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42							
Imipramine	No	111	111	101	93	87	82	79							
	Median	0.83	0.67	0.33	0.33	0.33	0.17	0.17							
	Min	0.17	0.00	0.00	0.00	0.00	0.00	0.00							
	Max	2.83	3.00	2.50	3.00	1.33	1.17	1.17							
	Median diff. vs day0 (*)		0.00	0.33	0.50	0.50	0.50	0.67							
Placebo	No	111	111	103	100	93	87	87							
	Median	0.83	0.67	0.50	0.50	0.33	0.33	0.33							
	Min	0.17	0.17	0.00	0.00	0.00	0.00	0.00							
	Max	3.00	2.83	2.83	2.00	2.00	1.50	1.50							
	Median diff. vs day0 (*)		0.17	0.17	0.33	0.33	0.33	0.50							
Reboxetine	No	110	110	105	98	97	90	89							
	Median	0.83	0.67	0.50	0.33	0.33	0.17	0.17							
	Min	0.17	0.00	0.00	0.00	0.00	0.00	0.00							
	Max	2.50	2.50	2.33	1.83	1.83	1.67	1.83							
	Median diff. vs day0 (*)		0.00	0.17	0.33	0.50	0.50	0.50							

Median (*): median of differences vs day0

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 20

FACTORIALISATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH FACTOR ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Factor: RETARDATION

Assigned treatment	Screen	Visit										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	
Imipramine	No	111	111	101	93	87	82	79				
	Median	2.00	2.00	1.75	1.50	1.00	1.00	0.50				
	Min	1.00	1.00	0.25	0.00	0.00	0.00	0.00				
	Max	3.25	3.25	3.25	3.25	2.50	2.00	2.00				
	Median diff. vs day0 (*)			0.25	0.50	0.75	1.00	1.25				
Placebo	No	111	111	103	100	93	87	87				
	Median	2.00	2.00	1.75	1.50	1.25	1.25	1.00				
	Min	1.25	1.25	0.50	0.00	0.00	0.00	0.00				
	Max	3.00	3.25	3.25	3.25	3.25	2.75	2.75				
	Median diff. vs day0 (*)			0.00	0.25	0.50	0.75	0.75				
Reboxetine	No	110	110	105	98	97	90	89				
	Median	2.25	2.13	2.00	1.50	1.00	1.00	0.75				
	Min	0.75	0.75	0.50	0.00	0.00	0.00	0.00				
	Max	3.25	3.25	3.00	3.00	3.00	2.75	2.50				
	Median diff. vs day0 (*)			0.25	0.50	0.75	1.00	1.25				

Median (*): median of differences vs day0

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 20

FACTORIZATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH FACTOR ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Factor: SLEEP DISTURRRANCE

Assigned treatment	Screen	Visit											
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	
Imipramino	No	111	111	101	93	87	82	79					
	Median	1.33	1.00	1.00	0.67	0.67	0.33	0.33					
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
	Max	2.00	2.00	2.00	2.00	2.00	2.00	2.00					
	Median diff. vs day0 (*)		0.00	0.33	0.67	0.67	0.67	1.00					
Placebo	No	111	111	103	100	93	87	87					
	Median	1.33	1.00	1.00	0.67	0.67	0.67	0.33					
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
	Max	2.00	2.00	2.00	2.00	2.00	2.00	2.00					
	Median diff. vs day0 (*)		0.00	0.33	0.67	0.67	0.67	1.00					
Reboxetine	No	110	110	105	98	97	90	89					
	Median	1.33	1.33	1.00	1.00	0.67	0.67	0.67					
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
	Max	2.00	2.00	2.00	2.00	2.00	2.00	2.00					
	Median diff. vs day0 (*)		0.00	0.33	0.67	0.67	0.67	1.00					

Median (*): median of differences vs day0

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: DEPRESSED MOOD

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	3	2	2	2	1	1	1			
	Min	1	0	0	0	0	0	0			
	Max	4	4	4	4	3	3	3			
Placebo	No	111	111	103	100	93	87	87			
	Median	3	3	2	2	1	2	1			
	Min	1	0	0	0	0	0	0			
	Max	4	4	4	4	4	4	4			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	3	2	2	2	1	1	1			
	Min	1	1	0	0	0	0	0			
	Max	4	4	4	4	4	4	4			

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: GUILT

Assigned treatment	Screen	Visit										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
Imipramine	No	111	111	101	93	87	82	79				
	Median	2	1	1	1	1	1	0				
	Min	0	0	0	0	0	0	0				
	Max	4	4	4	4	3	3	3				
Placebo	No	111	111	103	100	93	87	87				
	Median	2	2	1	1	1	1	1				
	Min	0	0	0	0	0	0	0				
	Max	4	4	3	3	3	3	3				
Reboxetine	No	110	110	105	98	97	90	89				
	Median	2	2	1	1	1	1	1				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	3	3	3				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: SUICIDE

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	1	1	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	4	3	3	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	1	1	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	3	3	4	4	3	3			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	1	1	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	3	3	3	3			

9550082

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: INSOMNIA EARLY

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	2	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	2	1	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	2	1	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: INSOMNIA MIDDLE

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	1	1	1	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	1	1	1	1	1	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	1	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 21

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: INSOMNIA LATE

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Inipramine	No	111	111	101	93	87	82	79			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	2	2	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT
HAMILTON DEPRESSION RATING SCALE

Item: WORK AND ACTIVITIES

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	3	2	2	1	1	1	1			
	Min	1	0	0	0	0	0	0			
	Max	4	4	4	4	4	3	3			
Placebo	No	111	111	103	100	93	87	87			
	Median	3	2	2	2	2	1	1			
	Min	1	1	0	0	0	0	0			
	Max	4	4	4	4	4	4	4			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	3	2	2	2	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	4	4	4	4	4	3	3			

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: RETARDATION

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	2	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	3	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	2	1	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	3	3	3	3			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	2	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	3	3	3	3			

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: AGITATION

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	1	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	4	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	1	1	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	3	3	2	3			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	1	1	1	1	1	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	4	4	4	2	2			

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: ANXIETY PSYCHIC

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	2	2	2	1	1	1	1			
	Min	1	1	0	0	0	0	0			
	Max	4	4	4	4	3	3	3			
Placebo	No	111	111	103	100	93	87	87			
	Median	2	2	2	2	1	1	1			
	Min	1	1	0	0	0	0	0			
	Max	4	4	4	4	4	3	3			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	2	2	2	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	4	4	4	4	4	3	3			

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 21

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: ANXIETY SOMATIC

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	2	2	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	3	4	4	4	2	3	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	2	2	2	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	4	4	4	3	3	3	3			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	2	2	1	1	1	1	1			
	Min	0	1	0	0	0	0	0			
	Max	4	4	4	4	3	3	2			

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: SOMATIC GASTROINTESTINAL

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	1	1	1	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: SOMATIC GENERAL

Assigned treatment	Screen	Visit											
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
Imipramine	No	111	111	101	93	87	82	79					
	Median	1	1	1	1	1	1	1					
	Min	0	0	0	0	0	0	0					
	Max	2	2	2	2	2	2	2					
Placebo	No	111	111	103	100	93	87	87					
	Median	1	1	1	1	1	1	1					
	Min	0	0	0	0	0	0	0					
	Max	2	2	2	2	2	2	2					
Reboxetine	No	110	110	105	98	97	90	89					
	Median	2	2	1	1	1	1	1					
	Min	0	0	0	0	0	0	0					
	Max	2	2	2	2	2	2	2					

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: GENITAL SYMPTOMS

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	1	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	1	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

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 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
 SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: HYPOCHONDRIASIS

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	1	1	1	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	3	3	3	3			
Placebo	No	111	111	103	100	93	87	87			
	Median	1	1	1	1	1	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	4	4	3	3	3			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	3	3	3	3			

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 21

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: LOSS OF WEIGHT

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	3	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	3	2	2	2			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	2	1	1	2			

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: INSIGHT

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2	2		
Placebo	No	111	111	103	100	93	87	87			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2	2		
Reboxetine	No	110	110	105	98	97	90	89			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2	2		

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: DIURNAL VARIATION

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	1	1	1	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2	2		
Placebo	No	111	111	103	100	93	87	87			
	Median	1	1	1	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2	2		
Reboxetine	No	110	110	105	98	97	90	89			
	Median	1	1	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2	2		

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: DEPERSONALIZATION

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	3	2	1	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	4	3	3	2	2			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	2	2	2	2			

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE:

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: PARANOIAD

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	2	1	1	1			
Placebo	No	111	111	103	100	93	87	87			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	2	2	1	1			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	1	1	1	1			

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 21

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: OBSESSIONAL/COMPULSIVE

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	111	111	101	93	87	82	79			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Placebo	No	111	111	103	100	93	87	87			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Reboxetine	No	110	110	105	98	97	90	89			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 22

HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON TOTAL SCORE AT LAST ASSESSMENT BY ASSIGNED TREATMENT

	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79	111				
	Mean	20.60	27.43	28.14	12.50	15.67	9.44	13.15				
	Median	23	25	28	13	18	9	10				
	STD	6.83	6.05	15.85	12.02	8.59	6.65	9.91				
	Min	9	19	10	4	4	0	0				
	Max	30	36	58	21	24	28	58				
	Mean diff. vs day0 (*)	4.20	-1.29	0.86	13.50	10.83	17.70	13.77				
Placebo	No	6	5	5	7	1	87	111				
	Mean	25.67	33.40	25.40	20.71	26.00	13.08	15.83				
	Median	27	33	28	24	26	11	13				
	STD	5.54	2.61	8.32	9.52		8.06	9.58				
	Min	16	30	11	4	26	1	1				
	Max	31	56	31	30	26	35	36				
	Mean diff. vs day0 (*)	5.00	-7.40	0.20	6.14	2.00	13.95	11.29				
Reboxetine	No	4	6	3	5	3	89	110				
	Mean	28.75	27.50	29.00	25.80	15.33	11.26	14.04				
	Median	29	28	29	23	11	10	12				
	STD	5.06	5.65	4.00	5.76	13.05	7.17	9.22				
	Min	23	18	25	21	5	0	0				
	Max	35	33	33	33	30	38	38				
	Mean diff. vs day0 (*)	-1.75	-2.17	-1.33	-0.20	10.00	16.62	13.49				

Mean (*): mean of differences vs day0

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 REBOXETINE - PROTOCOL 2012A/015
 TABLE No.: 23

FACTORIALISATION HAMILTON DEPRESSION RATING SCALE:
 SUMMARY STATISTICS ON SCORE OF EACH FACTOR AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Factor: ANXIETY/SOMATIZATION

Assigned treatment	Last assessment											Total
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	Day 77	
Imipramine	No	10	7	7	2	6	79	111				
	Median	1.33	1.50	1.50	0.50	1.00	0.50	0.67				0.67
	Min	0.33	1.17	0.33	0.17	0.17	0.00	0.00				0.00
	Max	1.67	2.00	2.67	0.83	1.50	2.00	2.67				2.67
	Median diff. vs day0 (*)	0.00	-0.17	-0.33	0.33	0.50	0.83	0.67				0.67
Placebo	No	6	5	5	7	1	87	111				
	Median	1.50	1.83	1.33	1.00	1.67	0.67	0.67				0.67
	Min	0.50	1.50	0.50	0.17	1.67	0.00	0.00				0.00
	Max	1.67	2.17	1.50	1.83	1.67	2.00	2.17				2.17
	Median diff. vs day0 (*)	0.00	-0.67	0.00	0.33	-0.17	0.67	0.50				0.50
Reboxetine	No	4	6	3	5	3	89	110				
	Median	1.75	1.67	1.50	1.00	0.83	0.50	0.83				0.83
	Min	1.67	1.17	0.83	0.83	0.00	0.00	0.00				0.00
	Max	2.00	2.33	1.83	1.67	1.83	1.83	2.33				2.33
	Median diff. vs day0 (*)	0.00	-0.08	-0.17	0.17	0.33	0.67	0.67				0.67

Median (*): mean of differences vs day0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 23

FACTORIZATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH FACTOR AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Factor: COGNITIVE DISTURBANCE

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	0.50	0.50	0.83	0.33	0.42	0.17					0.17
	Min	0.00	0.17	0.17	0.17	0.00	0.00					0.00
	Max	1.00	1.67	3.00	0.50	1.17	1.17					3.00
	Median diff. vs day0 (*)	0.00	0.17	0.00	0.42	0.50	0.67					0.50
Placebo	No	6	5	5	7	1	87					111
	Median	0.75	0.83	0.83	0.67	0.83	0.33					0.33
	Min	0.50	0.83	0.17	0.17	0.83	0.00					0.00
	Max	1.17	1.33	1.50	1.00	0.83	1.50					1.50
	Median diff. vs day0 (*)	0.00	-0.33	-0.17	0.00	0.00	0.50					0.33
Reboxetine	No	4	6	3	5	3	89					110
	Median	0.83	0.67	1.00	1.00	0.33	0.17					0.33
	Min	0.33	0.33	0.83	0.67	0.17	0.00					0.00
	Max	1.17	1.17	1.00	1.50	0.83	1.83					1.83
	Median diff. vs day0 (*)	-0.17	0.00	-0.17	-0.17	0.67	0.50					0.50

Median (*): mean of differences vs day0

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 23

FACTORIZATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH FACTOR AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Factor: RETARDATION

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70		
Imipramine	No	10	7	7	2	6	79	111				
	Median	1.50	2.00	2.00	1.25	1.50	0.50	1.00				
	Min	0.75	1.75	0.75	0.25	0.25	0.00	0.00				
	Max	2.75	3.00	3.25	2.25	1.75	2.00	3.25				
	Median diff. vs day0 (*)	0.13	0.25	0.00	1.50	0.50	1.25	1.00				
Placebo	No	6	5	5	7	1	87	111				
	Median	2.00	2.25	2.25	2.00	2.25	1.00	1.25				
	Min	1.00	2.00	1.50	0.25	2.25	0.00	0.00				
	Max	2.00	2.75	3.00	3.25	2.25	2.75	3.25				
	Median diff. vs day0 (*)	0.00	0.00	0.00	0.50	0.25	1.00	0.75				
Reboxetine	No	4	6	3	5	3	89	110				
	Median	2.13	2.38	2.00	1.75	0.75	0.75	1.00				
	Min	1.25	1.25	2.00	1.25	0.50	0.00	0.00				
	Max	2.75	2.75	2.25	2.75	2.00	2.50	2.75				
	Median diff. vs day0 (*)	0.13	-0.25	0.00	0.00	1.50	1.25	1.00				

Median (*): mean of differences vs day0

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REBOXETINE - PROTOCOL 2012A/015
TABLE No.: 23

FACTORIALISATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH FACTOR AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Factor: SLEEP DISTURBANCE

Assigned treatment	Last assessment										Total
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	
Imipramine	No	10	7	7	2	6	79	111			
	Median	1.33	2.00	1.33	0.67	0.67	0.33	0.67	0.33	0.67	0.67
	Min	0.33	0.00	0.67	0.33	0.00	0.00	0.00	0.00	0.00	0.00
	Max	2.00	2.00	2.00	1.00	1.00	2.00	2.00	2.00	2.00	2.00
	Median diff. vs day0 (*)	0.17	0.00	0.33	0.33	0.33	1.00	0.67	1.00	0.67	0.67
Placebo	No	6	5	5	7	1	87	111			
	Median	1.17	2.00	1.33	1.00	0.67	0.33	0.67	0.33	0.67	0.67
	Min	0.67	1.33	0.33	0.33	0.67	0.00	0.00	0.00	0.00	0.00
	Max	1.67	2.00	1.67	1.67	0.67	2.00	2.00	2.00	2.00	2.00
	Median diff. vs day0 (*)	0.00	-0.33	0.33	0.33	0.00	0.67	0.67	0.67	0.67	0.67
Reboxetine	No	4	6	3	5	3	89	110			
	Median	1.50	1.50	2.00	1.67	0.33	0.67	0.67	0.67	0.67	0.67
	Min	0.00	1.00	1.67	1.00	0.33	0.00	0.00	0.00	0.00	0.00
	Max	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
	Median diff. vs day0 (*)	0.00	-0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.67

Median (*): mean of differences vs day0

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: DEPRESSED MOOD

Assigned treatment		Last assessment								Total
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49		
Imipramine	No	10	7	7	2	6	79	111		
	Median	2	2	2	2	3	1	1		
	Min	1	2	1	0	0	0	0		
	Max	4	4	4	3	3	3	4		
Placebo	No	6	5	5	7	1	87	111		
	Median	2	3	3	2	2	1	2		
	Min	2	3	3	0	2	0	0		
	Max	3	4	3	4	2	4	4		
Reboxetine	No	4	6	3	5	3	89	110		
	Median	2	3	3	2	1	1	1		
	Min	1	2	2	1	1	0	0		
	Max	3	4	4	4	3	4	4		

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: GUILT

Assigned treatment	Last assessment										Total
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	
Imipramine	No	10	7	7	2	6	79				111
	Median	1	1	2	1	1	0				1
	Min	0	0	0	1	0	0				0
	Max	2	3	4	1	2	3				4
Placebo	No	6	5	5	7	1	87				111
	Median	2	2	2	1	2	1				1
	Min	1	1	1	0	2	0				0
	Max	2	3	3	2	2	3				3
Reboxetine	No	4	6	3	5	3	89				110
	Median	0	2	1	1	1	1				1
	Min	0	0	1	1	1	0				0
	Max	1	2	2	2	2	3				3

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: SUICIDE

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70		
Imipramine	No	10	7	7	2	6	79	111				
	Median	0	1	1	1	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	2	3	4	1	3	2	4				
Placebo	No	6	5	5	7	1	87	111				
	Median	1	2	2	1	2	0	0				
	Min	0	1	0	0	2	0	0				
	Max	2	3	4	4	2	3	4				
Reboxetine	No	4	6	3	5	3	89	110				
	Median	2	1	2	1	0	0	0				
	Min	0	0	1	0	0	0	0				
	Max	3	3	2	3	1	3	3				

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 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
 SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: INSOMNIA EARLY

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	2	2	1	1	1	0					1
	Min	0	0	1	0	0	0					0
	Max	2	2	2	1	1	2					2
Placebo	No	6	5	5	7	1	87					111
	Median	1	2	1	1	2	1					1
	Min	1	1	1	0	2	0					0
	Max	2	2	2	2	2	2					2
Reboxetine	No	4	6	3	5	3	89					110
	Median	2	2	2	2	1	1					1
	Min	0	1	1	0	0	0					0
	Max	2	2	2	2	2	2					2

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: INSOMNIA MIDDLE

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	1	2	1	1	1	0					0
	Min	0	0	0	0	0	0					0
	Max	2	2	2	1	1	2					2
Placebo	No	6	5	5	7	1	87					111
	Median	1	2	1	1	0	0					0
	Min	0	1	0	0	0	0					0
	Max	2	2	1	2	0	2					2
Reboxetine	No	4	6	3	5	3	89					110
	Median	2	2	2	2	1	0					1
	Min	0	1	2	1	0	0					0
	Max	2	2	2	2	2	2					2

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 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
 SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: INSOMNIA LATE

Assigned treatment	Last assessment											Total
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	1	2	1	1	1	0					0
	Min	0	0	1	1	0	0					0
	Max	2	2	2	1	1	2					2
Placebo	No	6	5	5	7	1	87					111
	Median	2	2	1	1	0	0					0
	Min	0	2	0	0	0	0					0
	Max	2	2	2	2	2	2					2
Reboxetine	No	4	6	3	5	3	89					110
	Median	1	2	2	1	0	1					1
	Min	0	0	2	1	0	0					0
	Max	2	2	2	2	2	2					2

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: HORK AND ACTIVITIES

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	2	3	4	2	2	1					1
	Min	1	2	1	1	0	0					0
	Max	4	4	4	3	3	3					4
Placebo	No	6	5	5	7	1	87					111
	Median	2	3	3	3	3	1					2
	Min	1	3	2	0	3	0					0
	Max	4	4	4	4	3	4					4
Reboxetine	No	4	6	3	5	3	89					110
	Median	4	3	3	2	1	1					1
	Min	2	2	2	2	1	0					0
	Max	4	4	3	4	2	3					4

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: RETARDATION

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	1	2	1	1	1	0					0
	Min	0	1	0	0	1	0					0
	Max	2	3	3	1	1	2					3
Placebo	No	6	5	5	7	1	87					111
	Median	1	1	1	1	2	1					1
	Min	0	0	0	0	2	0					0
	Max	2	3	3	3	2	3					3
Reboxetine	No	4	6	3	5	3	89					110
	Median	2	1	1	1	0	0					1
	Min	0	0	0	0	0	0					0
	Max	3	3	1	3	2	3					3

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: AGITATION

Assigned treatment	Last assessment									
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total			
Imipramine	No	10	7	7	2	6	79	111		
	Median	1	1	1	0	1	0	1		
	Min	0	0	0	0	0	0	0		
	Max	2	3	4	0	2	2	4		
Placebo	No	6	5	5	7	1	87	111		
	Median	2	2	0	1	0	1	1		
	Min	0	1	0	0	0	0	0		
	Max	2	3	1	3	0	3	3		
Reboxetine	No	4	6	3	5	3	89	110		
	Median	2	2	2	2	1	0	1		
	Min	2	0	2	1	0	0	0		
	Max	2	4	4	4	2	2	4		

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: ANXIETY PSYCHIC

Assigned treatment	Last assessment									
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total			
Imipramine	No	10	7	7	2	6	79	111		
	Median	2	2	3	0	2	1	1		
	Min	1	1	1	0	0	0	0		
	Max	3	4	4	0	3	3	4		
Placebo	No	6	5	5	7	1	87	111		
	Median	2	3	2	2	3	1	1		
	Min	1	3	1	0	3	0	0		
	Max	3	3	3	4	3	3	4		
Reboxetine	No	4	6	3	5	3	89	110		
	Median	3	3	2	2	1	1	1		
	Min	2	2	2	1	0	0	0		
	Max	4	4	4	4	2	3	4		

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: ANXIETY SOMATIC

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	2	3	2	2	1	1					1
	Min	0	1	1	1	0	0					0
	Max	3	4	4	2	2	2					4
Placebo	No	6	5	5	7	1	87					111
	Median	2	3	2	1	2	1					1
	Min	1	2	0	0	2	0					0
	Max	3	4	2	2	2	3					4
Reboxetine	No	4	6	3	5	3	89					110
	Median	3	2	3	2	2	1					1
	Min	2	2	0	0	0	0					0
	Max	3	4	4	3	2	2					4

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: SOMATIC GASTROINTESTINAL

Assigned treatment	Last assessment							Total
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0
	Max	1	2	2	2	1	2	2
Placebo	No	6	5	5	7	1	87	111
	Median	1	1	1	1	1	0	0
	Min	0	1	0	0	1	0	0
	Max	1	2	2	2	1	2	2
Reboxetine	No	4	6	3	5	3	89	110
	Median	1	2	1	1	1	0	0
	Min	1	0	1	0	0	0	0
	Max	2	2	2	2	2	2	2

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: SOMATIC GENERAL

	Last assessment									
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total			
Assigned treatment										
	Imipramine									
	No	10	7	7	2	6	79	111		
	Median	2	2	2	1	1	1	1		
Min	0	1	0	0	0	0	0			
Max	2	2	2	1	2	2	2			
Placebo	No	6	5	5	7	1	87	111		
	Median	2	2	1	1	1	1	1		
	Min	1	2	1	0	1	0	0		
	Max	2	2	2	2	1	2	2		
Reboxetine	No	4	6	3	5	3	89	110		
	Median	2	2	2	1	1	1	1		
	Min	1	1	1	0	0	0	0		
	Max	2	2	2	1	2	2	2		

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE.
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: GENITAL SYMPTOMS

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	1	1	1	1	1	0					1
	Min	0	0	0	0	0	0					0
	Max	2	2	2	2	1	2					2
Placebo	No	6	5	5	7	1	87					111
	Median	2	2	2	2	2	0					1
	Min	0	0	0	0	0	0					0
	Max	2	2	2	2	2	2					2
Reboxetine	No	4	6	3	5	3	89					110
	Median	2	2	2	1	1	0					1
	Min	1	1	2	0	0	0					0
	Max	2	2	2	2	1	2					2

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: HYPOCHONDRIASIS

Assigned treatment	Last assessment									
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total			
Imipramine	No	10	7	7	2	6	79	111		
	Median	0	1	1	0	2	0	0		
	Min	0	0	0	0	0	0	0		
	Max	2	3	3	0	3	3	3		
Placebo	No	6	5	5	7	1	87	111		
	Median	2	2	1	0	3	0	1		
	Min	0	1	0	0	3	0	0		
	Max	2	3	2	2	3	3	3		
Reboxetine	No	4	6	3	5	3	89	110		
	Median	2	2	0	1	0	0	0		
	Min	1	0	0	0	0	0	0		
	Max	3	3	1	2	3	3	3		

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: LOSS OF WEIGHT

Assigned treatment	Last assessment										Total
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	
Imipramine	No	10	7	7	2	6	79				111
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	0	2	3	0	0	2				3
Placebo	No	6	5	5	7	1	87				111
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	1	1	0	0	2				2
Reboxetine	No	4	6	3	5	3	89				110
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	0	0	1	0	0	2				2

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: INSIGHT

	Assigned treatment							Last assessment						
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111						
	Median	0	0	0	0	0	0	0						
	Min	0	0	0	0	0	0	0						
	Max	1	0	1	0	0	2	2						
Placebo	No	6	5	5	7	1	87	111						
	Median	0	0	0	0	0	0	0						
	Min	0	0	0	0	0	0	0						
	Max	0	1	1	2	0	2	2						
Reboxetine	No	4	6	3	5	3	89	110						
	Median	0	0	0	0	0	0	0						
	Min	0	0	0	0	0	0	0						
	Max	1	0	0	1	0	2	2						

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE.
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: DIURNAL VARIATION

Assigned treatment		Last assessment							Total
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
Imipramine	No	10	7	7	2	6	79	111	
	Median	1	0	1	1	1	0	0	
	Min	0	0	0	0	0	0	0	
	Max	2	2	2	1	1	2	2	
Placebo	No	6	5	5	7	1	87	111	
	Median	2	1	0	0	0	0	0	
	Min	0	0	0	0	0	0	0	
	Max	2	2	2	1	0	2	2	
Reboxetine	No	4	6	3	5	3	89	110	
	Median	1	0	1	1	0	0	0	
	Min	1	0	0	0	0	0	0	
	Max	2	1	1	2	1	2	2	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: DEPERSONALIZATION

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
Imipramine	No	10	7	7	2	6	79					111
	Median	0	0	0	1	0	0					0
	Min	0	0	0	0	0	0					0
	Max	1	0	3	1	0	2					3
Placebo	No	6	5	5	7	1	87					111
	Median	0	0	0	0	0	0					0
	Min	0	0	0	0	0	0					0
	Max	1	0	1	1	0	2					2
Reboxetine	No	4	6	3	5	3	89					110
	Median	0	0	0	1	0	0					0
	Min	0	0	0	0	0	0					0
	Max	0	0	0	1	0	2					2

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE.
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: PARANOID

Assigned treatment	Last assessment									
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total			
Imipramine	No	10	7	7	2	6	79	111		
	Median	0	0	0	0	0	0	0		
	Min	0	0	0	0	0	0	0		
	Max	1	1	2	0	0	1	2		
Placebo	No	6	5	5	7	1	87	111		
	Median	0	0	0	0	0	0	0		
	Min	0	0	0	0	0	0	0		
	Max	1	0	2	1	0	1	2		
Reboxetine	No	4	6	3	5	3	89	110		
	Median	0	0	0	1	0	0	0		
	Min	0	0	0	0	0	0	0		
	Max	0	0	0	1	0	1	1		

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PHARMACIA CNS RD

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE.
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: OBSESSIONAL/COMPULSIVE

Assigned treatment	Last assessment									
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total			
Imipramine	No	7	7	2	6	79	111			
	Median	0	0	0	0	0	0			
	Min	0	0	0	0	0	0			
	Max	1	1	2	0	1	2			
Placebo	No	5	5	7	1	87	111			
	Median	0	0	0	0	0	0			
	Min	0	0	0	0	0	0			
	Max	1	1	1	1	2	2			
Reboxetine	No	6	6	3	5	89	110			
	Median	1	0	0	0	0	0			
	Min	0	0	0	0	0	0			
	Max	2	0	0	0	0	2			

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 25

EFFICACY: CLASSIFICATION OF PATIENTS ACCORDING TO PROTOCOL CRITERIA ON TOTAL SCORE OF HAMILTON DEPRESSION RATING SCALE OVER TIME BY ASSIGNED TREATMENT

Assigned treatment		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	Patients No.	111	101	93	87	82	79
	Responders No.	8	23	45	52	53	62
	Responders %	7.2	22.8	48.4	59.8	64.6	78.5
	95% L.L.	3.2	15.0	37.9	48.7	53.3	67.8
	95% U.L.	13.7	32.2	59.0	70.1	74.9	86.9
	Remissions No.	8	9	29	40	46	50
	Remissions %	7.2	8.9	31.2	46.0	56.1	63.3
	95% L.L.	3.2	4.2	22.0	35.2	44.7	51.7
	95% U.L.	13.7	16.2	41.6	57.0	67.0	73.9
Placebo	Patients No.	111	103	100	93	87	87
	Responders No.	5	10	33	42	45	54
	Responders %	4.5	9.7	33.0	45.2	51.7	62.1
	95% L.L.	1.5	4.8	23.9	34.8	40.8	51.0
	95% U.L.	10.2	17.1	43.1	55.8	62.6	72.3
	Remissions No.	1	5	14	27	32	39
	Remissions %	0.9	4.9	14.0	29.0	36.8	44.8
	95% L.L.	0.0	1.6	7.9	20.1	26.7	34.1
	95% U.L.	4.9	11.0	22.4	39.4	47.8	55.9
Reboxetine	Patients No.	110	105	98	97	90	89
	Responders No.	5	21	38	46	59	63
	Responders %	4.5	20.0	38.8	47.4	65.6	70.8
	95% L.L.	1.5	12.8	29.1	37.2	54.8	60.2
	95% U.L.	10.3	28.9	49.2	57.8	75.3	79.9
	Remissions No.	1	12	27	32	40	46
	Remissions %	0.9	11.4	27.6	33.0	44.4	51.7
	95% L.L.	0.0	6.0	19.0	23.8	34.0	40.8
	95% U.L.	5.0	19.1	37.5	43.3	55.3	62.4

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 26
 EFFICACY: CLASSIFICATION OF PATIENTS ACCORDING TO PROTOCOL CRITERIA ON TOTAL SCORE OF HAMILTON DEPRESSION RATING SCALE
 AT LAST ASSESSMENT VERSUS DAY 0 BY ASSIGNED TREATMENT

	Assigned treatment	
	Imipramine	Reboxetine
Patients No.	111	110
Responders No.	69	65
Responders %	62.2	59.1
95% L.L.	52.5	49.3
95% U.L.	71.2	68.4
Remissions No.	56	47
Remissions %	50.5	42.7
95% L.L.	40.8	33.3
95% U.L.	60.1	52.5

COMPARISON BETWEEN TREATMENTS

RESPONSE : Reboxetine vs Placebo Adj. Chi-square = 0.788 Prob. = 0.375
 Imipramine vs Placebo Adj. Chi-square = 1.840 Prob. = 0.175

REMISSION: Reboxetine vs Placebo Adj. Chi-square = 0.775 Prob. = 0.379
 Imipramine vs Placebo Adj. Chi-square = 4.129 Prob. = 0.042

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 27

CLINICAL GLOBAL IMPRESSION: SEVERITY OF ILLNESS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment/Severity of illness	Visit														
	Day 0		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		
	No	%	No	%	No	%	No	%	No	%	No	%	No	%	
Imipramine	NORMAL		2	1.8	2	2.0	6	6.4	7	8.0	11	13.1	20	25.3	
	BORDERLINE MENTALLY ILL		4	3.6	4	4.0	13	13.8	22	25.3	27	32.1	25	31.6	
	MILDLY ILL	2	1.8	10	9.0	21	20.8	38	40.4	35	40.2	28	33.3	24	30.4
	MODERATELY ILL	29	26.1	43	38.7	47	46.5	24	25.5	18	20.7	14	16.7	8	10.1
	MARKEDLY ILL	64	57.7	45	40.5	23	22.8	8	8.5	5	5.7	4	4.8	2	2.5
	SEVERELY ILL	15	13.5	7	6.3	4	4.0	4	4.3						
	EXTREMELY ILL	1	0.9					1	1.1						
	Total	111	100.0	111	100.0	104	100.0	94	100.0	87	100.0	84	100.0	79	100.0
Placebo	NORMAL							2	2.0	6	6.4	8	9.2	13	14.9
	BORDERLINE MENTALLY ILL			1	0.9	4	3.8	8	8.1	17	18.1	18	20.7	20	23.0
	MILDLY ILL	4	3.6	10	9.0	17	16.3	30	30.3	26	27.7	28	32.2	22	25.3
	MODERATELY ILL	38	34.2	47	42.3	44	42.3	36	36.4	24	25.5	24	27.6	24	27.6
	MARKEDLY ILL	51	45.9	43	38.7	30	28.8	16	16.2	12	12.8	6	6.9	6	6.9
	SEVERELY ILL	18	16.2	10	9.0	9	8.7	7	7.1	8	8.5	3	3.4	2	2.3
	EXTREMELY ILL									1	1.1				
	Total	111	100.0	111	100.0	104	100.0	99	100.0	94	100.0	87	100.0	87	100.0
Reboxetine	NORMAL					1	1.0	5	5.1	8	8.2	13	14.4	15	16.9
	BORDERLINE MENTALLY ILL			3	2.7	8	7.6	18	18.4	27	27.8	28	31.1	32	36.0
	MILDLY ILL	1	0.9	9	8.2	25	24.8	28	28.6	22	22.7	24	26.7	20	22.5
	MODERATELY ILL	33	29.7	46	41.8	36	34.3	29	29.5	27	27.8	18	20.0	16	18.0
	MARKEDLY ILL	54	48.6	37	33.6	26	24.8	15	15.3	10	10.3	5	5.6	4	4.5
	SEVERELY ILL	22	19.8	15	13.6	8	7.6	3	3.1	3	3.1	2	2.2	2	2.2
	EXTREMELY ILL	1	0.9												
	Total	111	100.0	111	100.0	104	100.0	99	100.0	94	100.0	87	100.0	87	100.0

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PHARMACIA CNS R80

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 27

CLINICAL GLOBAL IMPRESSION: SEVERITY OF ILLNESS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment/Severity of illness	Visit													
	Day 0		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42	
	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Reboxetine	111	100.0	110	100.0	105	100.0	98	100.0	97	100.0	90	100.0	89	100.0
Total														

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 29

CLINICAL GLOBAL IMPRESSION: SEVERITY OF ILLNESS SHIFT TABLE (LAST VALUE VS DAY 0) BY ASSIGNED TREATMENT

Assigned treatment/Shift severity	Total			Last visit																		
	No	Z	%	Day 7			Day 14			Day 21			Day 28			Day 35			Day 42			
				No	Z	%	No	Z	%	No	Z	%	No	Z	%	No	Z	%	No	Z	%	
Imipramine	DECREASED	86	77.5	4	40.0				3	37.5	1	50.0	4	66.7	74	93.7						
	NO CHANGE	20	18.0	6	60.0	5	83.3	3	37.5	1	50.0	1	16.7	4	5.1							
	INCREASED	5	4.5			1	16.7	2	25.0						1	1.3						
	Total	111	100.0	10	100.0	6	100.0	8	100.0	2	100.0	6	100.0	6	100.0	79	100.0					
Placebo	DECREASED	73	65.8	1	16.7										70	80.5						
	NO CHANGE	23	26.1	4	66.7	2	40.0	2	50.0	5	62.5	1	100.0	15	17.2							
	INCREASED	9	8.1	1	16.7	3	60.0	2	50.0	1	12.5			2	2.3							
	Total	111	100.0	6	100.0	5	100.0	4	100.0	8	100.0	8	100.0	1	100.0	87	100.0					
Reboxetine	DECREASED	85	77.3			2	33.3	1	33.3	1	20.0	2	66.7	79	88.8							
	NO CHANGE	19	17.3	3	75.0							2	66.7	4	80.0							
	INCREASED	6	5.5	1	25.0	4	66.7							1	33.3							
	Total	110	100.0	4	100.0	6	100.0	3	100.0	5	100.0	5	100.0	3	100.0	89	100.0					

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 2012/015

TABLE No.: 30

CLINICAL GLOBAL IMPRESSION: GLOBAL IMPROVEMENT ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment/Global improvement	Visit												
	Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		
	No	%	No	%	No	%	No	%	No	%	No	%	
Imipramine	VERY MUCH IMPROVED	2	1.8	2	2.0	12	12.8	15	17.2	20	23.8	31	39.2
	MUCH IMPROVED	12	10.8	32	31.7	43	45.7	44	50.6	40	47.6	34	43.0
	MINIMALLY IMPROVED	44	39.6	40	39.6	21	22.3	19	21.8	14	16.7	8	10.1
	NO CHANGE	44	39.6	20	19.8	11	11.7	5	5.7	9	10.7	3	3.8
	MINIMALLY WORSE	7	6.3	5	5.0	2	2.1	2	2.3			2	2.5
	MUCH WORSE	2	1.8	2	2.0	4	4.3	2	2.3	1	1.2	1	1.3
	VERY MUCH WORSE					1	1.1						
	Total	111	100.0	104	100.0	94	100.0	87	100.0	84	100.0	79	100.0
	VERY MUCH IMPROVED	1	0.9	1	1.0	4	4.0	10	10.6	13	14.9	18	20.7
	MUCH IMPROVED	8	7.2	20	19.2	29	29.3	34	36.2	35	40.2	36	41.4
MINIMALLY IMPROVED	32	28.8	38	36.5	34	34.3	27	28.7	26	29.9	20	23.0	
NO CHANGE	58	52.3	36	34.6	24	24.2	15	16.0	9	10.3	9	10.3	
MINIMALLY WORSE	11	9.9	3	2.9	6	6.1	2	2.1	2	2.3	1	1.1	
MUCH WORSE	1	0.9	6	5.8	2	2.0	5	5.3	2	2.3	3	3.4	
VERY MUCH WORSE							1	1.1					
Total	111	100.0	104	100.0	99	100.0	94	100.0	87	100.0	87	100.0	
VERY MUCH IMPROVED	3	2.7	6	5.7	17	17.3	22	22.7	25	27.8	31	34.8	
MUCH IMPROVED	7	6.4	27	25.7	30	30.6	37	38.1	42	46.7	34	38.2	
MINIMALLY IMPROVED	43	39.1	43	41.0	31	31.6	22	22.7	13	14.4	15	16.9	
NO CHANGE	45	40.9	21	20.0	14	14.3	9	9.3	5	5.6	5	5.6	
MINIMALLY WORSE	10	9.1	4	3.8	6	6.1	6	6.2	4	4.4	4	4.5	
MUCH WORSE	2	1.8	4	3.8			1	1.0	1	1.1			
Total	110	100.0	105	100.0	98	100.0	97	100.0	90	100.0	89	100.0	
Reboxetine													

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REBOXETINE - PROTOCOL 20124/015
TABLE No. : 32

CLINICAL GLOBAL IMPRESSION: EFFICACY INDEX
ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment / Efficacy index (*)	Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		
	No	%	No	%	No	%	No	%	No	%	No	%	
Imipramine	< 1	28	25.2	12	11.9	10	10.6	7	8.0	5	6.0	4	5.1
	1	50	45.0	34	33.7	17	18.1	8	9.2	6	7.1	4	5.1
	1.33 - 1.5	8	7.2	17	16.8	20	21.3	16	18.4	12	14.3	10	12.7
	2	17	15.3	23	22.8	23	24.5	31	35.6	31	36.9	29	36.7
	3	6	5.4	12	11.9	18	19.1	16	18.4	17	20.2	16	20.3
4	2	1.8	3	3.0	6	6.4	9	10.3	13	15.5	16	20.3	
Total	111	100	101	100	94	100	87	100	84	100	79	100	
Placebo	< 1	18	16.2	13	12.5	11	11.1	10	10.6	3	3.4	2	2.3
	1	61	55.0	43	41.3	28	28.3	19	20.2	17	19.5	17	19.5
	1.33 - 1.5	6	5.4	9	8.7	8	8.1	7	7.4	13	14.9	6	6.9
	2	20	18.0	22	21.2	24	24.2	24	25.5	19	21.8	19	21.8
	3	5	4.5	15	14.4	21	21.2	18	19.1	14	16.1	20	23.0
4	1	0.9	2	1.9	7	7.1	16	17.0	21	24.1	23	26.4	
Total	111	100	104	100	99	100	94	100	87	100	87	100	
Reboxetine	< 1	26	23.4	16	15.2	9	9.2	7	7.2	4	4.4	3	3.4
	1	51	45.9	32	30.5	22	22.4	16	16.5	11	12.2	10	11.2
	1.33 - 1.5	4	3.6	11	10.5	10	10.2	11	11.3	6	6.7	8	9.0
	2	21	18.9	25	23.8	26	26.5	27	27.8	23	25.6	19	21.3
	3	8	7.2	17	16.2	21	21.4	22	22.7	24	26.7	17	19.1
4	1	0.9	4	3.8	10	10.2	14	14.4	22	24.4	32	36.0	
Total	111	100	105	100	98	100	97	100	90	100	89	100	

EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 33

CLINICAL GLOBAL IMPRESSION: EFFICACY INDEX AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Assigned treatment / Efficacy index (*)	total		Last Assessment													
			Day 7		Day 14		Day 21		Day 28		Day 35		Day 42			
	No	%	No	%	No	%	No	%	No	%	No	%	No	%		
Imipramine	< 1	18	16.22	5	50.00	4	66.67	3	37.50			2	33.33	4	5.06	
	1	15	13.51	2	20.00	1	16.67	5	62.50	1	50.00	2	33.33	4	5.06	
	1.33 - 1.5	12	10.81	2	20.00									10	12.66	
	2	33	29.73	1	10.00	1	16.67			1	50.00	1	16.67	29	36.71	
	3	17	15.32										1	16.67	16	20.25
	4	16	14.41												16	20.25
Total	111	100.0	10	100.0	6	100.0	8	100.0	2	100.0	6	100.0	79	100.0		
Placebo	< 1	15	13.51	2	33.33	4	80.00	2	50.00	4	50.00	1	100.0	2	2.30	
	1	24	21.62	3	50.00	1	20.00	1	25.00	2	25.00			37	19.54	
	1.33 - 1.5	6	5.41											6	6.90	
	2	20	18.02							1	12.50			19	21.84	
	3	21	18.92					1	25.00					20	22.99	
	4	25	22.52	1	16.67					1	12.50			23	26.44	
Total	111	100.0	6	100.0	5	100.0	4	100.0	8	100.0	1	100.0	87	100.0		
Reboxetine	< 1	17	15.32	5	100.0	4	66.67	2	66.67	3	60.00			3	3.37	
	1	15	13.51			2	33.33	1	33.33	1	20.00	1	33.33	10	11.24	
	1.33 - 1.5	10	9.01							1	20.00	1	33.33	8	8.99	
	2	20	18.02									1	33.33	19	21.35	
	3	17	15.32											17	19.10	
	4	32	28.83											32	35.96	
Total	111	100.0	5	100.0	6	100.0	3	100.0	5	100.0	3	100.0	89	100.0		

EFFICACY INDEX (*): computed from the vector activity by the vector side effects

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 34

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON TOTAL SCORE ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Mean	16.74	14.36	11.96	9.60	7.79	6.81	5.84
	Median	16	14	12	9	7	6	5
	STD	3.41	4.52	4.97	5.18	4.00	3.87	4.00
	Min	8	1	0	0	0	0	0
	Max	26	25	26	28	21	19	20
	Mean diff. vs day0 (*)		2.38	4.87	7.21	8.89	9.79	10.95
Placebo	No	111	111	103	100	92	87	87
	Mean	16.28	14.77	13.57	11.31	9.91	8.30	7.73
	Median	16	15	14	11	9	8	7
	STD	3.45	4.07	4.77	4.98	5.71	4.98	4.91
	Min	8	5	3	2	0	0	0
	Max	25	25	25	26	25	21	21
	Mean diff. vs day0 (*)		1.51	2.63	4.90	6.35	7.74	8.17
Reboxetine	No	110	110	105	98	97	90	89
	Mean	16.38	14.55	12.39	9.96	8.75	7.14	6.62
	Median	16	15	13	10	9	7	6
	STD	3.92	4.33	5.10	5.23	5.07	4.76	4.73
	Min	7	3	0	0	0	0	0
	Max	26	25	25	25	25	25	25
	Mean diff. vs day0 (*)		1.82	4.07	6.60	7.77	9.49	9.87

Mean (*): mean of differences vs day0

PHARMACIA CNS R550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: REPORTED SADNESS

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Median	2	2	2	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	2	3
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	2	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	2	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS ~~905~~50082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: INNER TENSION

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Inipramine	No	111	111	101	93	87	84	79
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	2
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	2	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	1	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	3	2

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PHARMACIA CNS ~~05~~50082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: APPARENT SADNESS

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Median	2	2	1	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	2	2
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	2	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	1	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

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PHARMACIA CNS R050082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: SUICIDAL THOUGHTS

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Median	1	1	1	0	0	0	0
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	2	2	2
Placebo	No	111	111	103	100	92	87	87
	Median	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3
Reboxetine	No	110	110	105	98	97	90	89
	Median	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	2

PHARMACIA CNS R9550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: INNER TENSION

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Inipramine	No	111	111	101	93	87	84	79
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	2
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	2	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	1	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	3	2

PHARNACTA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: INERTIA

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	2
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS R550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: INABILITY TO FEEL

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	2	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	3	2	2
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS R550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: PESSIMISTIC THOUGHTS

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Median	2	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	2	2	2
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	2
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	2	2	2

PHARMACIA CNS 0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: CONCENTRATIONS DIFFICULTIES

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Median	2	2	1	1	1	1	1
	Min	1	0	0	0	0	0	0
	Max	3	3	3	3	2	2	2
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	2	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	2
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: REDUCED SLEEP

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	84	79
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	2	2	2
Placebo	No	111	111	103	100	92	87	87
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	2	3	2	2
Reboxetine	No	110	110	105	98	97	90	89
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	3

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PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: REDUCED APPETITE

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Inipramine	No	111	111	101	93	87	84	79
	Median	1	1	1	0	0	0	0
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	2	2	3
Placebo	No	111	111	103	100	92	87	87
	Median	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0
	Max	2	2	3	2	2	2	2
Reboxetine	No	110	110	105	98	97	90	89
	Median	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0
	Max	3	3	2	2	2	2	2

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 36

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON TOTAL SCORE AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Mean	13.50	17.00	17.50	11.00	7.58	5.84	8.15
	Median	14	19	20	11	7	5	7
	STD	3.96	5.07	8.04	12.73	5.42	4.00	6.12
	Min	8	11	6	2	2	0	0
	Max	20	24	28	20	15	20	28
	Mean diff. vs day0 (*)	2.40	0.21	0.86	8.50	6.67	10.95	8.59
Placebo	No	6	5	5	7	1	87	111
	Mean	14.33	21.60	17.70	16.29	21.00	7.73	9.82
	Median	16	21	19	18	21	7	8
	STD	4.59	2.41	7.03	8.32		4.91	6.57
	Min	6	19	7	3	21	0	0
	Max	18	25	26	25	21	21	26
	Mean diff. vs day0 (*)	2.67	-4.80	-0.40	2.43	-1.00	8.17	6.46
Reboxetine	No	4	6	3	5	3	89	110
	Mean	16.75	18.00	17.33	16.10	10.33	6.62	8.44
	Median	17	20	17	16	7	6	7
	STD	4.03	3.74	2.52	5.27	9.45	4.73	6.09
	Min	12	12	15	11	3	0	0
	Max	21	22	20	23	21	25	25
	Mean diff. vs day0 (*)	-2.00	-2.17	-2.33	0.40	7.00	9.87	7.94

Mean (*): mean of differences vs day0

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: REPORTED SADNESS

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	2	2	2	2	1	1	1
	Min	1	1	1	0	0	0	0
	Max	3	3	3	3	2	3	3
Placebo	No	6	5	5	7	1	87	111
	Median	2	3	3	2	3	1	1
	Min	1	2	1	0	3	0	0
	Max	2	3	3	3	3	3	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	2	2	2	2	1	1	1
	Min	1	2	2	1	1	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS R09550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: INNER TENSION

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	2	2	2	1	1	1	1
	Min	1	2	1	0	0	0	0
	Max	3	3	3	1	2	2	3
Placebo	No	6	5	5	7	1	87	111
	Median	2	3	2	2	2	1	1
	Min	1	2	1	1	2	0	0
	Max	3	3	3	3	2	3	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	2	2	2	2	1	1	1
	Min	1	2	2	2	1	0	0
	Max	3	3	3	3	3	2	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: APPARENT SADNESS

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	2	2	2	1	1	1	1
	Min	1	2	1	0	0	0	0
	Max	2	3	3	2	2	2	3
Placebo	No	6	5	5	7	1	87	111
	Median	2	3	2	2	3	1	1
	Min	1	2	1	0	3	0	0
	Max	2	3	3	3	3	3	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	2	2	2	2	0	1	1
	Min	1	2	2	1	0	0	0
	Max	2	2	3	2	3	3	3

PHARMACIA CNS R20550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: SUICIDAL THOUGHTS

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	2	2	1	1	0	0
	Min	0	0	0	0	0	0	0
	Max	2	3	3	1	2	2	3
Placebo	No	6	5	5	7	1	87	111
	Median	1	1	2	1	2	0	1
	Min	0	1	0	0	2	0	0
	Max	2	2	3	3	2	3	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	2	2	1	3	0	0	0
	Min	0	0	1	1	0	0	0
	Max	3	2	2	3	1	2	3

PHARMACIA CNS R&D 550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: INERTIA

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	2	2	2	0	1	1
	Min	0	1	0	1	0	0	0
	Max	2	3	3	2	1	2	3
Placebo	No	6	5	5	7	1	87	111
	Median	2	2	2	2	2	1	1
	Min	1	2	1	0	2	0	0
	Max	2	3	3	3	2	3	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	2	2	1	2	1	1	1
	Min	1	0	1	1	1	0	0
	Max	2	3	2	3	2	3	3

PHARMACIA CNS R&D 9550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: INABILITY TO FEEL

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	2	1	2	2	1	1	1
	Min	1	1	1	0	0	0	0
	Max	2	2	3	3	2	3	3
Placebo	No	6	5	5	7	1	87	111
	Median	2	2	2	2	1	1	1
	Min	0	1	1	0	1	0	0
	Max	2	2	2	3	1	2	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	2	2	2	1	0	1	1
	Min	1	1	1	1	0	0	0
	Max	3	2	2	3	2	3	3

PHARMACIA CNS R550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: PESSIMISTIC THOUGHTS

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	2	2	1	1	1	1
	Min	1	1	0	0	0	0	0
	Max	2	3	3	2	2	2	3
Placebo	No	6	5	5	7	1	87	111
	Median	2	2	2	2	2	1	1
	Min	0	1	1	0	2	0	0
	Max	2	2	3	3	2	2	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	1	2	1	1	1	1	1
	Min	0	1	1	1	0	0	0
	Max	2	2	2	2	2	2	2

PHARMACIA CNS 09550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: CONCENTRATIONS DIFFICULTIES

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	2	1	1	1	1
	Min	1	1	0	0	1	0	0
	Max	2	2	3	2	2	2	3
Placebo	No	6	5	5	7	1	87	111
	Median	2	2	2	2	3	1	1
	Min	1	2	1	1	3	0	0
	Max	3	3	2	3	3	2	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	2	2	1	2	1	1	1
	Min	2	1	1	1	0	0	0
	Max	2	3	2	3	2	3	3

PHARMACIA CNS 0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No. 1 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: REDUCED SLEEP

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipranine	No	10	7	7	2	6	79	111
	Median	2	2	2	2	1	1	1
	Min	1	0	1	1	0	0	0
	Max	3	3	2	2	1	2	3
Placebo	No	6	5	5	7	1	87	111
	Median	2	3	2	2	2	1	1
	Min	1	2	0	1	2	0	0
	Max	2	3	2	3	2	2	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	2	2	2	2	1	1	1
	Min	0	1	2	1	0	0	0
	Max	3	3	3	3	2	3	3

PHARMACIA CNS R550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 37

MONTGOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: REDUCED APPETITE

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	2	1	0	0	0
	Min	1	0	0	0	0	0	0
	Max	2	2	3	2	1	3	3
Placebo	No	6	5	5	7	1	87	111
	Median	1	2	2	1	1	0	0
	Min	0	0	0	0	1	0	0
	Max	2	3	2	2	1	2	3
Reboxetine	No	4	6	3	5	3	89	110
	Median	1	2	1	1	1	0	0
	Min	0	0	1	0	0	0	0
	Max	3	2	1	1	1	2	3

PHARMACIA CNS R&D 550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 38

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON TOTAL SCORE ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Mean	18.59	16.02	13.61	11.27	8.93	8.02	6.46
	Median	18	17	13	11	8	8	6
	STD	6.18	6.74	6.67	6.96	6.05	5.73	5.32
	Min	4	0	0	0	0	0	0
	Max	40	37	33	36	29	22	22
	Mean diff. vs day0 (*)		2.58	5.13	7.70	10.07	11.02	12.67
Placebo	No	111	111	103	100	93	87	86
	Mean	18.00	16.05	14.99	12.60	11.75	9.98	9.43
	Median	18	15	14	12	10	10	8
	STD	7.04	7.12	7.44	7.71	8.16	7.48	7.47
	Min	2	0	0	0	0	0	0
	Max	44	43	41	33	31	32	33
	Mean diff. vs day0 (*)		1.95	3.11	5.55	6.72	8.36	8.79
Reboxetine	No	109	109	103	97	96	89	88
	Mean	18.80	16.08	13.88	10.77	9.97	8.07	7.59
	Median	18	16	13	11	10	7	7
	STD	6.96	7.60	7.57	7.52	7.50	6.63	6.87
	Min	1	0	0	0	0	0	0
	Max	40	39	38	36	35	32	34
	Mean diff. vs day0 (*)		2.72	5.10	8.38	9.26	11.24	11.66

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: FACIAL EXPRESSION

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	2	2	1	1	1	1	0
	Min	0	0	0	0	0	0	0
	Max	4	3	3	3	3	3	2
Placebo	No	111	111	103	100	93	87	86
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	4	4	4
Reboxetine	No	109	109	103	97	96	89	88
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	4	4	4

PHARMACIA CNS REF 550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: BODY GESTURES

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	2	1	1	1	1	1	0
	Min	0	0	0	0	0	0	0
	Max	3	4	3	3	3	3	2
Placebo	No	111	111	103	100	93	87	86
	Median	2	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	3	3	3	3	3
Reboxetine	No	109	109	103	97	96	89	88
	Median	2	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: LOOK

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	2
Placebo	No	111	111	103	100	93	87	86
	Median	1	1	1	1	1	1	0
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	3	3	3
Reboxetine	No	109	109	103	97	96	89	88
	Median	1	1	1	1	1	0	0
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	4	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: OUTWARD APPEARANCE

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0
	Max	4	4	3	3	3	2	2
Placebo	No	111	111	103	100	93	87	86
	Median	1	1	1	1	1	0	0
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	3	2	2
Reboxetine	No	109	109	103	97	96	89	88
	Median	1	1	1	1	1	0	0
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: SPEECH

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	2	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	2
Placebo	No	111	111	103	100	93	87	86
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	3	3	3	3	3
Reboxetine	No	109	109	103	97	96	89	88
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	3	3	3	3	3

PHARMACIA CNS R09550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: VOICE

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	1	1	1	1	1	0	0
	Min	0	0	0	0	0	0	0
	Max	4	4	3	3	2	2	2
Placebo	No	111	111	103	100	93	87	86
	Median	1	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	3	3	3
Reboxetine	No	109	109	103	97	96	89	88
	Median	1	1	1	1	1	1	0
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	3	2	2

PHARMACIA CNS 0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: ADAPTABILITY, SUGGESTIBILITY

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Inipramine	No	111	111	101	93	87	82	79
	Median	2	1	1	1	1	1	0
	Min	0	0	0	0	0	0	0
	Max	4	3	3	3	2	3	2
Placebo	No	111	111	103	100	93	87	86
	Median	2	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	3	3	3	3	3	4
Reboxetine	No	109	109	103	97	96	89	88
	Median	2	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: CONTACTS, AFFECTIVE NEED

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	3	3	3	3	3
Placebo	No	111	111	103	100	93	87	86
	Median	2	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	4	4
Reboxetine	No	109	109	103	97	96	89	88
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	3	3	3	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: ANGUISH, ANXIETY

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	3	3	3
Placebo	No	111	111	103	100	93	87	86
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	4	4	4	3	3
Reboxetine	No	109	109	103	97	96	89	88
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	3	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: AGGRESSION, IRRITABILITY

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0
	Max	3	3	4	3	2	2	3
Placebo	No	111	111	103	100	93	87	86
	Median	1	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	3	2	2
Reboxetine	No	109	109	103	97	96	89	88
	Median	1	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	4	4	3	3	3	2	2

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: SELF-AGGRESSION

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	1	1	1	1	1	1	0
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	2
Placebo	No	111	111	103	100	93	87	86
	Median	1	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	4	3	2
Reboxetine	No	109	109	103	97	96	89	88
	Median	1	1	1	1	1	0	0
	Min	0	0	0	0	0	0	0
	Max	4	4	4	3	3	3	3

PHARMACIA CNS R09550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 39

RELATIONAL DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Item: GLOBAL EVALUATION

Assigned treatment		Visit						
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Imipramine	No	111	111	101	93	87	82	79
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	2
Placebo	No	111	111	103	100	93	87	86
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3
Reboxetine	No	109	109	103	97	96	89	88
	Median	2	2	1	1	1	1	1
	Min	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3

PHARMACIA CNS 0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: BODY GESTURES

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	2	1	1	2	0	1
	Min	0	1	1	0	0	0	0
	Max	2	3	3	1	2	2	3
Placebo	No	6	5	5	7	2	86	111
	Median	2	2	1	2	1	1	1
	Min	1	0	0	0	0	0	0
	Max	2	3	2	2	2	3	3
Reboxetine	No	4	6	3	5	3	88	109
	Median	2	2	1	2	1	1	1
	Min	1	1	1	1	0	0	0
	Max	3	3	1	3	2	3	3

PHARMACIA CNS R550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 40

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON TOTAL SCORE AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Mean	13.50	19.29	19.14	7.50	14.17	6.46	9.14
	Median	14	18	19	8	19	6	8
	STD	6.75	6.50	8.97	9.19	7.96	5.32	7.44
	Min	2	12	8	1	3	0	0
	Max	24	32	36	14	21	22	36
	Mean diff. vs day0 (*)	3.60	-3.43	-0.71	12.00	3.00	12.67	9.46
Placebo	No	6	5	5	7	2	86	111
	Mean	14.00	19.00	16.20	17.29	18.00	9.43	11.06
	Median	15	22	14	20	18	8	10
	STD	6.23	5.20	8.04	7.93	14.14	7.47	7.96
	Min	6	10	5	3	8	0	0
	Max	21	22	25	25	28	33	33
	Mean diff. vs day0 (*)	4.33	-4.40	-1.00	1.86	1.00	8.79	6.94
Reboxetine	No	4	6	3	5	3	88	109
	Mean	21.00	19.00	15.00	20.40	10.67	7.59	9.59
	Median	22	20	15	20	6	7	8
	STD	7.07	5.48	1.00	8.99	11.72	6.87	8.10
	Min	12	11	14	8	2	0	0
	Max	29	24	16	30	24	34	34
	Mean diff. vs day0 (*)	-3.50	-2.83	-3.00	-0.20	6.33	11.66	9.21

Mean (*): mean of differences vs day0

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: LOOK

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	2	1	1	0	0
	Min	0	1	0	0	0	0	0
	Max	2	2	3	1	1	2	3
Placebo	No	6	5	5	7	2	86	111
	Median	1	1	1	2	1	0	1
	Min	0	0	0	0	0	0	0
	Max	1	2	2	2	2	3	3
Reboxetine	No	4	6	3	5	3	88	109
	Median	1	1	1	2	1	0	1
	Min	0	1	1	0	0	0	0
	Max	1	2	1	4	2	3	4

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: OUTHARD APPEARANCE

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	1	1	0	0	0
	Min	0	1	0	0	0	0	0
	Max	2	3	3	1	1	2	3
Placebo	No	6	5	5	7	2	86	111
	Median	1	1	1	1	1	0	1
	Min	0	1	0	0	0	0	0
	Max	1	2	2	2	2	2	2
Reboxetine	No	4	6	3	5	3	88	109
	Median	1	2	0	1	1	0	0
	Min	0	1	0	0	0	0	0
	Max	1	3	2	3	2	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEN AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: SPEECH

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	2	2	1	2	2	1	1
	Min	0	1	1	0	0	0	0
	Max	2	3	3	3	2	2	3
Placobo	No	6	5	5	7	2	86	111
	Median	2	2	2	2	2	1	1
	Min	0	1	1	0	1	0	0
	Max	2	3	3	3	3	3	3
Reboxetine	No	4	6	3	5	3	88	109
	Median	2	2	2	2	0	1	1
	Min	2	1	2	1	0	0	0
	Max	3	3	2	3	2	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: VOICE

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	2	1	1	2	0	1
	Min	0	1	1	0	1	0	0
	Max	2	2	3	1	2	2	3
Placebo	No	6	5	5	7	2	86	111
	Median	1	1	1	2	2	1	1
	Min	0	0	1	0	1	0	0
	Max	2	2	2	2	2	3	3
Reboxetine	No	4	6	3	5	3	88	109
	Median	2	2	1	2	0	0	1
	Min	0	0	0	0	0	0	0
	Max	2	2	2	3	2	2	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: ADAPTABILITY, SUGGESTIBILITY

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	1	1	2	0	1
	Min	0	1	0	0	0	0	0
	Max	2	3	3	2	2	2	3
Placebo	No	6	5	5	7	2	86	111
	Median	1	1	2	2	1	1	1
	Min	1	0	0	0	0	0	0
	Max	2	2	2	2	2	4	4
Reboxetine	No	4	6	3	5	3	88	109
	Median	2	2	1	1	1	1	1
	Min	2	1	0	1	0	0	0
	Max	3	2	2	3	2	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: CONTACTS, AFFECTIVE NEED

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	2	1	1	2	1	1
	Min	0	1	1	0	0	0	0
	Max	3	3	3	1	3	3	3
Placebo	No	6	5	5	7	2	86	111
	Median	2	2	1	2	2	1	1
	Min	0	0	1	0	0	0	0
	Max	2	2	3	3	3	4	4
Reboxetine	No	4	6	3	5	3	88	109
	Median	3	2	1	2	1	1	1
	Min	2	0	1	1	1	0	0
	Max	3	3	1	3	2	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: ANGUISH, ANXIETY

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	2	2	1	1	1	1
	Min	0	1	1	1	0	0	0
	Max	3	3	3	1	3	3	3
Placebo	No	6	5	5	7	2	86	111
	Median	2	3	2	2	2	1	1
	Min	1	2	0	1	1	0	0
	Max	3	4	3	4	3	3	4
Reboxetine	No	4	6	3	5	3	88	109
	Median	3	2	2	2	1	1	1
	Min	2	2	2	0	0	0	0
	Max	3	4	3	3	2	3	4

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: GLOBAL EVALUATION

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	2	1	1	1	1
	Min	0	1	1	0	0	0	0
	Max	2	2	3	1	3	2	3
Placebo	No	6	5	5	7	2	86	111
	Median	2	2	0	2	2	1	1
	Min	0	1	0	0	1	0	0
	Max	2	2	3	2	2	3	3
Reboxetine	No	4	6	3	5	3	88	109
	Median	2	2	1	2	1	1	1
	Min	1	0	1	1	0	0	0
	Max	2	2	2	3	2	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE

SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: SELF-AGGRESSION

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	1	0	1	0	1
	Min	1	0	1	0	0	0	0
	Max	2	2	3	0	3	2	3
Placebo	No	6	5	5	7	2	86	111
	Median	1	1	2	1	2	1	1
	Min	0	0	1	1	1	0	0
	Max	2	3	3	4	3	2	4
Reboxetine	No	4	6	3	5	3	88	109
	Median	2	1	1	1	0	0	1
	Min	1	0	1	1	0	0	0
	Max	3	3	1	3	2	3	3

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 41

RELATIONAL DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: GLOBAL EVALUATION

Assigned treatment		Last assessment						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total
Imipramine	No	10	7	7	2	6	79	111
	Median	1	1	2	1	1	1	1
	Min	0	1	1	0	0	0	0
	Max	2	2	3	1	3	2	3
Placebo	No	6	5	5	7	2	86	111
	Median	2	2	0	2	2	1	1
	Min	0	1	0	0	1	0	0
	Max	2	2	3	2	2	3	3
Reboxetine	No	4	6	3	5	3	88	109
	Median	2	2	1	2	1	1	1
	Min	1	0	1	1	0	0	0
	Max	2	2	2	3	2	3	3

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PHARMACIA CNS R8D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 42
 ADVERSE EVENTS: FREQUENCY (95% C.I.) OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT DURING THERAPY
 BY SEX AND ASSIGNED TREATMENT

	Assigned treatment											
	Imipramine			Placebo			Reboxetine					
	Female	Male	Total	Female	Male	Total	Female	Male	Total	Female	Male	Total
Pt exposed	77	38	115	54	58	112	70	42	112			
Pt with adverse events	54	27	81	29	29	58	44	27	71			
X on exposed	70.12	71.05	70.43	53.70	50.00	51.78	62.85	64.28	63.39			
95% L.L.	58.62	54.10	61.21	39.61	36.58	42.15	50.48	48.03	53.76			
95% U.L.	80.03	84.58	78.58	67.38	63.42	61.33	74.11	78.45	72.29			
No. of adverse events	218	70	288	78	63	141	136	75	211			
Ratio A.E. on Pt with A.E.	4.03	2.59	3.55	2.68	2.17	2.43	3.09	2.77	2.97			

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PHARMACIA CHS RRD
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 43
 ADVERSE EVENTS: FREQUENCY (95% C.I.) OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT DURING THERAPY
 BY AGE AND ASSIGNED TREATMENT

	Assigned treatment															
	Imipramine							Placebo								
	Total	18 - 30	31 - 45	> 45	Total	18 - 30	31 - 45	> 45	Total	18 - 30	31 - 45	> 45	Total	18 - 30	31 - 45	> 45
Pt exposed	115	17	44	54	112	15	50	47	112	14	41	57	112	14	41	57
Pt with adverse events	81	12	31	38	58	8	28	22	71	10	29	32	71	10	29	32
% on exposed	70.43	70.58	70.45	70.37	51.78	53.33	56.00	46.80	63.39	71.42	70.73	56.14	63.39	71.42	70.73	56.14
95% L.L.	61.21	44.04	54.80	56.39	42.15	26.59	41.25	32.11	53.76	41.90	54.46	42.36	53.76	41.90	54.46	42.36
95% U.L.	78.55	89.69	83.24	82.02	61.39	78.73	70.01	61.92	72.29	91.61	83.87	69.26	72.29	91.61	83.87	69.26
No. of adverse events	288	44	123	121	141	20	74	47	211	32	83	96	211	32	83	96
Ratio A.E. on Pt with A.E.	3.55	3.66	3.96	3.18	2.43	2.50	2.64	2.13	2.97	3.20	2.86	3.00	2.97	3.20	2.86	3.00

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 44
 ADVERSE EVENTS: FREQUENCY (95% C.I.) OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT DURING THERAPY
 BY DSM III CLASSIFICATION AND ASSIGNED TREATMENT

	Assigned treatment											
	Inipramine						Reboxetine					
	Total	296.2	296.3	296.5	Total	296.2	296.3	Total	296.2	296.3	296.5	
Pt exposed	115	34	80	1	112	30	82	112	35	76	1	
Pt with adverse events	81	24	56	1	58	12	46	71	20	51	0	
% on exposed	70.43	70.58	70.00	100.00	51.78	40.00	56.09	63.39	57.14	67.10	0.00	
95% L.L.	61.21	52.52	58.72	5.00	42.15	22.66	44.70	53.76	39.36	55.37	0.00	
95% U.L.	78.58	84.90	79.74	100.00	61.33	59.40	67.05	72.29	73.66	77.46	95.00	
No. of adverse events	288	82	204	2	141	19	122	211	53	158	0	
Ratio A.E. on Pt with A.E.	3.55	3.41	3.64	2.00	2.43	1.58	2.65	2.97	2.65	3.09		

272

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female					Male					Total					
	No of Pt. exp.	% on exp.	No of Pt. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp.	No of Pt. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp.	No of Pt. with AE	No of AE	Ratio (*)	
Pt exposed	Imipramine	77	100.0			38	100.0				115	100.0				
	Placebo	54	100.0			58	100.0				112	100.0				
	Reboxetine	70	100.0			42	100.0				112	100.0				
Pt with a.e.	Imipramine	54	70.1	100.0	218	4.03	27	71.1	100.0	70	2.59	81	70.4	100.0	288	3.55
	Placebo	29	53.7	100.0	78	2.68	29	50.0	100.0	63	2.17	58	51.8	100.0	141	2.43
	Reboxetine	44	62.9	100.0	136	3.09	27	64.3	100.0	75	2.77	71	63.4	100.0	211	2.97
MOUTH DRY	Imipramine	35	45.5	64.8	38	1.08	14	36.8	51.8	15	1.07	49	42.6	60.4	53	1.08
	Placebo	10	18.5	34.4	10	1.00	4	6.9	13.7	5	1.25	14	12.5	24.1	15	1.07
	Reboxetine	19	27.1	43.1	20	1.05	9	21.4	33.3	9	1.00	28	25.0	39.4	29	1.03
CONSTIPATION	Imipramine	14	18.2	25.9	14	1.00	4	10.5	14.8	4	1.00	18	15.7	22.2	18	1.00
	Placebo	5	9.3	17.2	5	1.00	1	1.7	3.4	1	1.00	6	5.4	10.3	6	1.00
	Reboxetine	12	17.1	27.2	14	1.16	5	11.9	18.5	6	1.20	17	15.2	23.9	20	1.17
SWEATING INCREASED	Imipramine	16	20.8	29.6	20	1.25	6	15.8	22.2	6	1.00	22	19.1	27.1	26	1.18
	Placebo	2	3.7	6.8	2	1.00	1	1.7	3.4	1	1.00	3	2.7	5.1	3	1.00
	Reboxetine	11	15.7	25.0	12	1.09	3	7.1	11.1	3	1.00	14	12.5	19.7	15	1.07
HEADACHE	Imipramine	7	9.1	12.9	7	1.00	2	5.3	7.4	2	1.00	9	7.8	11.1	9	1.00
	Placebo	3	5.6	10.3	4	1.33	6	10.3	20.6	6	1.00	9	8.0	15.5	10	1.11
	Reboxetine	10	14.3	22.7	14	1.40	4	9.5	14.8	4	1.00	14	12.5	19.7	18	1.28
TREMOR	Imipramine	16	20.8	29.6	16	1.00	4	10.5	14.8	4	1.00	20	17.4	24.6	20	1.00
	Placebo	2	3.7	6.8	2	1.00	3	5.2	10.3	3	1.00	5	4.5	8.6	5	1.00
	Reboxetine	4	5.7	9.0	4	1.00	2	4.8	7.4	2	1.00	6	5.4	8.4	6	1.00
NAUSEA	Imipramine	11	14.3	20.3	13	1.18	2	5.3	7.4	3	1.50	13	11.3	16.0	16	1.23

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female					Male					Total					
	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)
NAUSEA	Placabo	8	14.8	27.5	10	1.25	1	1.7	3.4	1	1.00	9	8.0	15.5	11	1.22
	Reboxetine	6	8.6	13.6	6	1.00	3	7.1	11.1	3	1.00	9	8.0	12.6	9	1.00
DIZZINESS	Imipramine	10	13.0	18.5	12	1.20	4	10.5	14.8	4	1.00	14	12.2	17.2	16	1.14
	Placabo						4	6.9	13.7	4	1.00	4	3.6	6.8	4	1.00
INSOMNIA	Reboxetine	3	4.3	6.8	4	1.33	3	7.1	11.1	4	1.33	6	5.4	8.4	8	1.33
	Imipramine	6	7.8	11.1	6	1.00	2	5.3	7.4	2	1.00	8	7.0	9.8	8	1.00
AGITATION	Placabo	2	3.7	6.8	2	1.00	2	3.4	6.8	2	1.00	4	3.6	6.8	4	1.00
	Reboxetine	7	10.0	15.9	7	1.00	5	11.9	18.5	5	1.00	12	10.7	16.9	12	1.00
VISION ABNORMAL	Imipramine	2	2.6	3.7	2	1.00	2	5.3	7.4	2	1.00	4	3.5	4.9	4	1.00
	Placabo	1	1.9	3.4	1	1.00	6	10.3	20.6	6	1.00	7	6.3	12.0	7	1.00
SOMNOLENCE	Reboxetine	4	5.7	9.0	4	1.00	3	7.1	11.1	4	1.33	7	6.3	9.8	8	1.14
	Imipramine	6	7.8	11.1	7	1.16	3	7.9	11.1	3	1.00	9	7.8	11.1	10	1.11
VERTIGO	Placabo						3	5.2	10.3	3	1.00	3	2.7	5.1	3	1.00
	Reboxetine	3	4.3	6.8	3	1.00	3	7.1	11.1	4	1.33	6	5.4	8.4	7	1.16
FATIGUE	Imipramine	4	5.2	7.4	4	1.00	2	5.3	7.4	2	1.00	6	5.2	7.4	6	1.00
	Placabo	4	7.4	13.7	5	1.25	5	8.6	17.2	5	1.00	9	8.0	15.5	10	1.11
FATIGUE	Reboxetine	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
	Imipramine	7	9.1	12.9	8	1.14						7	6.1	8.6	8	1.14
FATIGUE	Reboxetine	4	5.7	9.0	4	1.00	1	2.4	3.7	1	1.00	5	4.5	7.0	5	1.00
	Imipramine	3	3.9	5.5	3	1.00	1	2.6	3.7	1	1.00	4	3.5	4.9	4	1.00
FATIGUE	Placabo	1	1.9	3.4	1	1.00	3	5.2	10.3	3	1.00	4	3.6	6.8	4	1.00
	Reboxetine	1	1.4	2.2	1	1.00	2	4.8	7.4	2	1.00	3	2.7	4.2	3	1.00

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female					Male					Total								
	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (%)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (%)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (%)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (%)			
PARAESTHESIA	Imipramine	5	6.5	9.2	5	1.00	1	1.00	1	2.6	3.7	1	1.00	6	5.2	7.4	6	1.00	
	Placebo	1	1.9	3.4	1	1.00	1	1.00	1	1.7	3.4	1	1.00	2	1.8	3.4	2	1.00	
	Reboxetine	1	1.4	2.2	1	1.00	1	1.00	1	2.4	3.7	1	1.00	2	1.8	2.8	2	1.00	
SUICIDE ATTEMPT	Imipramine	2	2.6	3.7	2	1.00	2	1.00	2	5.3	7.4	2	1.00	4	3.5	4.9	4	1.00	
	Placebo	3	5.6	10.3	3	1.00	1	1.00	1	1.7	3.4	1	1.00	4	3.6	6.8	4	1.00	
	Reboxetine	1	1.4	2.2	1	1.00								1	0.9	1.4	1	1.00	
HYPOTENSION POSTURAL	Imipramine	5	6.5	9.2	5	1.00	1	1.00	1	2.6	3.7	1	1.00	6	5.2	7.4	6	1.00	
	Reboxetine	2	2.9	4.5	2	1.00								2	1.8	2.8	2	1.00	
	Imipramine	3	3.9	5.5	4	1.33	1	1.00	1	2.6	3.7	1	1.00	4	3.5	4.9	5	1.25	
ABDOMINAL PAIN	Placebo	2	3.7	6.8	2	1.00	1	1.00	1	1.7	3.4	1	1.00	3	2.7	5.1	3	1.00	
	Reboxetine	1	1.4	2.2	1	1.00								1	0.9	1.4	1	1.00	
	Imipramine	4	5.2	7.4	4	1.00								4	3.5	4.9	4	1.00	
TACHYCARDIA	Reboxetine	2	2.9	4.5	2	1.00	1	1.00	1	2.4	3.7	1	1.00	3	2.7	4.2	3	1.00	
	Imipramine	2	2.6	3.7	2	1.00								2	1.7	2.4	2	1.00	
	Placebo						4	6.9	13.7	4	6.9	13.7	4	3.6	6.8	4	1.00		
RHINITIS	Reboxetine	1	1.4	2.2	1	1.00								1	0.9	1.4	1	1.00	
	Imipramine						1	2.6	3.7	1	2.6	3.7	1	1.00	1	0.9	1.2	1	1.00
	Placebo	4	7.4	13.7	4	1.00								4	3.6	6.8	4	1.00	
VOMITING	Reboxetine						1	2.6	3.7	1	2.6	3.7	1	1.00	1	0.9	1.2	1	1.00
	Imipramine																		
	Placebo	4	7.4	13.7	4	1.00								4	3.6	6.8	4	1.00	
DYSPEPSIA	Reboxetine																		
	Imipramine	4	5.2	7.4	4	1.00	1	1.00	1	2.4	3.7	1	1.00	1	0.9	1.4	1	1.00	
	Placebo	1	1.9	3.4	1	1.00								5	4.3	6.1	5	1.00	
HOT FLUSHES	Placebo	2	2.6	3.7	2	1.00	1	1.00	1	2.6	3.7	1	1.00	1	0.9	1.7	1	1.00	
	Imipramine													3	2.6	3.7	4	1.33	

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female					Male					Total					
	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)
HOT FLUSHES	1	1.9	3.4	1.00					1	0.9	1.7	1.00				
	1	1.4	2.2	1.00	1	2.4	3.7	1.00	2	1.8	2.8	1.00				
HYPOTENSION	1	1.3	1.8	1.00									1	0.9	1.2	1.00
	1	1.9	3.4	1.00	1	1.7	3.4	1.00	2	1.8	3.4	1.00				
ANXIETY	1	1.4	2.2	1.00	1	2.4	3.7	1.00	1	0.9	1.2	1.00				
	2	3.7	6.8	1.00	1	2.6	3.7	1.00	3	2.7	5.1	1.00				
NERVOUSNESS	1	1.9	3.4	1.00					1	0.9	1.4	1.00				
	3	4.3	6.8	1.00	1	2.4	3.7	1.00	4	3.6	5.6	1.00				
DYSPNOEA	2	2.6	3.7	1.00					2	1.7	2.4	1.00				
	3	4.3	6.8	1.66					3	2.7	4.2	1.66				
MICTURITION DISORDER	1	1.3	1.8	1.00					1	0.9	1.2	1.00				
	1	1.9	3.4	1.00					1	0.9	1.7	1.00				
URINARY TRACT INFECTION	1	1.9	3.4	1.00	3	7.1	11.1	1.00	3	2.7	4.2	1.00				
	4	5.7	9.0	1.00					1	0.9	1.7	1.00				
URINARY RETENTION	1	1.9	3.4	1.00	1	1.7	3.4	1.00	1	0.9	1.7	1.00				
	4	5.7	9.0	1.00	3	7.1	11.1	1.00	3	2.7	4.2	1.00				
PALPITATION	1	1.3	1.8	1.00	1	2.6	3.7	1.00	2	1.7	2.4	1.00				
	1	1.4	2.2	1.00	1	1.7	3.4	1.00	1	0.9	1.7	1.00				

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/015
TABLE No.: 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female						Male						Total					
	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp. with AE	No of AE	Ratio (*)		
ASTHENIA	1	1.3	1.8	1.00	2	5.3	7.4	2	1.00	3	2.6	3.7	3	3.7	3	1.00		
	1	1.4	2.2	1.00						1	0.9	1.4	1	1.4	1	1.00		
RASH	1	1.3	1.8	1.00						1	0.9	1.2	1	1.2	1	1.00		
	2	3.7	6.8	2	1.00					2	1.8	3.4	2	3.4	2	1.00		
NYALGIA					1	2.6	3.7	1	1.00	1	0.9	1.2	1	1.2	1	1.00		
					2	3.4	6.8	2	1.00	2	1.8	3.4	2	3.4	2	1.00		
CONFUSION	2	2.6	3.7	2	1.00					2	1.7	2.4	2	2.4	2	1.00		
					1	2.4	3.7	1	1.00	1	0.9	1.4	1	1.4	1	1.00		
HYPERKINESIA	1	1.3	1.8	1	1.00					1	0.9	1.2	1	1.2	1	1.00		
	1	1.9	3.4	1	1.00	1	1.7	3.4	1	1.00	2	1.8	3.4	2	1.00			
MUSCLE CONTRACTIONS INVOLUNTARY					2	5.3	7.4	2	1.00	2	1.7	2.4	2	2.4	2	1.00		
	1	1.4	2.2	1	1.00					1	0.9	1.4	1	1.4	1	1.00		
DIARRHOEA	1	1.9	3.4	1	1.00	2	3.4	6.8	2	1.00	3	2.7	5.1	3	1.00			
	2	2.6	3.7	2	1.00					2	1.7	2.4	2	2.4	2	1.00		
APPETITE INCREASED	1	1.9	3.4	1	1.00					1	0.9	1.2	1	1.2	1	1.00		
	2	2.6	3.7	2	1.00					2	1.7	2.4	2	2.4	2	1.00		
WEIGHT INCREASE	1	1.4	2.2	1	1.00					1	0.9	1.4	1	1.4	1	1.00		
					1	1.7	3.4	1	1.00	1	0.9	1.2	1	1.2	1	1.00		
SINUSITIS	2	2.9	4.5	2	1.00					2	1.8	2.8	2	2.8	2	1.00		
					1	2.6	3.7	1	1.00	1	0.9	1.2	1	1.2	1	1.00		
DYSURIA					2	4.8	7.4	2	1.00	2	1.8	2.8	2	2.8	2	1.00		

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female					Male					Total				
	No of Pt. exp.	% on exp.	No of AE	No of Pt. with AE	Ratio (*)	No of Pt. exp.	% on exp.	No of AE	No of Pt. with AE	Ratio (*)	No of Pt. exp.	% on exp.	No of AE	No of Pt. with AE	Ratio (*)
CHEST PAIN PRECORDIAL	2	2.6	3.7	2	1.00						2	1.7	2.4	2	1.00
	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
INFLUENZA-LIKE SYMPTOMS	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
						1	1.7	3.4	1	1.00	1	0.9	1.7	1	1.00
ARTHRALGIA	1	1.9	3.4	1	1.00						1	0.9	1.4	1	1.00
						1	2.4	3.7	1	1.00	1	0.9	1.7	1	1.00
BACK PAIN	2	3.7	6.8	2	1.00						2	1.8	3.4	2	1.00
	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
HYPERTENSION											1	2.4	3.7	1	1.00
						1	2.4	3.7	1	1.00	2	1.8	2.8	2	1.00
HYDRIASIS	1	1.4	2.2	1	1.00						2	1.7	2.4	2	1.00
	2	2.6	3.7	2	1.00						2	1.7	2.4	2	1.00
CONJUNCTIVITIS	1	1.3	1.8	1	1.00						1	0.9	1.7	1	1.00
	1	1.9	3.4	1	1.00						1	0.9	1.4	1	1.00
FLATULENCE	1	1.4	2.2	1	1.00						1	0.9	1.2	1	1.00
	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
GAMMA-GT INCREASED						1	2.4	3.7	1	1.00	1	0.9	1.4	1	1.00
						1	1.7	3.4	1	1.00	1	0.9	1.7	1	1.00
WEIGHT DECREASE	1	1.4	2.2	1	1.00						2	1.7	2.4	2	1.00
	2	2.6	3.7	2	1.00						1	0.9	1.2	1	1.00
SYNCOPE	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female					Male					Total					
	No of Pt. exp.	% on exp.	No of AE	Ratio (*)	No of Pt.	% on exp.	No of AE	Ratio (*)	No of Pt. exp.	% on exp.	No of AE	Ratio (*)	No of Pt. exp.	% on exp.	No of AE	Ratio (*)
RASH ERYTHEMATOUS	1	1.4	2.2	1.00									1	0.9	1.4	1.00
PRURITIS	1	1.3	1.8	1.00									1	0.9	1.2	1.00
COLD URTICARIA					1	2.6	3.7	1.00					1	0.9	1.2	1.00
HYPERTONIA	1	1.9	3.4	1.00									1	0.9	1.7	1.00
MIGRAINE					1	2.4	3.7	1.00					1	0.9	1.4	1.00
SPEECH DISORDER	1	1.3	1.8	1.00									1	0.9	1.2	1.00
ANOREXIA	1	1.4	2.2	1.00									1	0.9	1.4	1.00
ACCOMMODATION ABNORMAL	1	1.3	1.8	1.00									1	0.9	1.2	1.00
FLUSHING	1	1.4	2.2	1.00									1	0.9	1.4	1.00
BRADYCARDIA	1	1.9	3.4	1.00									1	0.9	1.7	1.00
SALIVA INCREASED					1	2.4	3.7	1.00					1	0.9	1.4	1.00
CHROMATOPSIA	1	1.9	3.4	1.00									1	0.9	1.7	1.00
EYE ABNORMALITY	1	1.4	2.2	1.00									1	0.9	1.4	1.00
TASTE LOSS	1	1.3	1.8	1.00									1	0.9	1.2	1.00
TASTE PERVERSION	1	1.9	3.4	1.00									1	0.9	1.7	1.00
AUTOLESIONIST BEHAVIOUR	1	1.3	1.8	1.00									1	0.9	1.2	1.00
DEPERSONALIZATION	1	1.3	1.8	1.00									1	0.9	1.2	1.00
LIBIDO DECREASED					1	2.4	3.7	1.00					1	0.9	1.4	1.00
PARONYCHIA	1	1.9	3.4	1.00									1	0.9	1.7	1.00
SLEEP DISORDER	1	1.3	1.8	1.00									1	0.9	1.2	1.00

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CHS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female					Male					Total				
	No of Pt. exp.	% on exp.	No of AE with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp.	No of AE with AE	No of AE	Ratio (*)	No of Pt. exp.	% on exp.	No of AE with AE	No of AE	Ratio (*)
DEPRESSION AGGRAVATED	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
CONCENTRATION IMPAIRED	1	1.9	1.8	1	1.00						1	0.9	1.2	1	1.00
COLITIS						1	2.6	3.7	1	1.00	1	0.9	1.2	1	1.00
DUODENAL ULCER REACTIVATED	1	1.9	1.8	1	1.00						1	0.9	1.2	1	1.00
DYSPLAGIA						1	2.6	3.7	1	1.00	1	0.9	1.2	1	1.00
GASTRITIS	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
GASTROENTERITIS	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
TONGUE ULCERATION						1	1.7	3.4	1	1.00	1	0.9	1.7	1	1.00
TOOTH DISORDER	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
HYPERURICAEMIA						1	2.4	3.7	1	1.00	1	0.9	1.4	1	1.00
HYPOKALAEMIA	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
PHOSPHATASE ALKALINE INCREASED	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
HYPERTRIGLYCERIDAEMIA	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
EXTRASYSTOLES	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
HAEMORRHOIDS THROMBOSIS	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
BRONCHITIS	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
ANAEMIA HIPOCHROMIC	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
EOSINOPHILIA	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 45

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt. exp.	% on Pt. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on Pt. with AE	No of AE	Ratio (*)	No of Pt. exp.	% on Pt. with AE	No of AE	Ratio (*)
MICTURITION FREQUENCY												
			Placebo									
			Reboxetine									
PYURIA	1	1.4	2.2	1.00					1	0.9	1.7	1.00
			Reboxetine						1	0.9	1.4	1.00
IMPOTENCE												
			Reboxetine									
PERINEAL PAIN MALE												
			Reboxetine									
EPIDIDYMITIS												
			Reboxetine									
MALaise												
			Placebo									
			Inipramine									
RIGORS												
			Reboxetine									
HYPERPYREXIA	1	1.4	2.2	1.00					1	0.9	1.2	1.00
			Placebo									
PHARYNGITIS												
			Placebo									
HERPES SIMPLEX	1	1.9	3.4	1.00					1	0.9	1.7	1.00
			Placebo									

(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: AUTONOMIC NERVOUS SYSTEM DISORDERS

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)
MOUTH DRY	35	45.5	64.8	38 1.08	14	36.8	51.8	15 1.07	49	42.6	60.4	53 1.08
	10	18.5	34.4	10 1.00	4	6.9	13.7	5 1.25	14	12.5	24.1	15 1.07
	19	27.1	43.1	20 1.05	9	21.4	33.3	9 1.00	28	25.0	39.4	29 1.03
SWEATING INCREASED	16	20.8	29.6	20 1.25	6	15.8	22.2	6 1.00	22	19.1	27.1	26 1.18
	2	3.7	6.8	2 1.00	1	1.7	3.4	1 1.00	3	2.7	5.1	3 1.00
	11	15.7	25.0	12 1.09	3	7.1	11.1	3 1.00	14	12.5	19.7	15 1.07
SALIVA INCREASED					1	2.4	3.7	1 1.00	1	0.9	1.4	1 1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No. : 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: BODY AS A WHOLE-GENERAL DISORDERS

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt exp.	% on exp.	No of Pt with AE	Ratio No of AE (*)	No of Pt exp.	% on exp.	No of Pt with AE	Ratio No of AE (*)	No of Pt exp.	% on exp.	No of Pt with AE	Ratio No of AE (*)
ASTHENIA / FATIGUE	3	3.9	5.5	4 1.33	3	7.9	11.1	3 1.00	6	5.2	7.4	7 1.16
	1	1.9	3.4	1 1.00	3	5.2	10.3	3 1.00	4	3.6	6.8	4 1.00
	2	2.9	4.5	2 1.00	2	4.8	7.4	2 1.00	4	3.6	5.6	4 1.00
INFLUENZA-LIKE SYMPTOMS	1	1.3	1.8	1 1.00					1	0.9	1.2	1 1.00
					1	1.7	3.4	1 1.00	1	0.9	1.7	1 1.00
CHEST PAIN					1	2.4	3.7	1 1.00	1	0.9	1.4	1 1.00
	1	1.3	1.8	1 1.00					1	0.9	1.2	1 1.00
HYPERPYREXIA	1	1.4	2.2	1 1.00					1	0.9	1.4	1 1.00
	1	1.4	2.2	1 1.00					1	0.9	1.4	1 1.00
RIGORS					1	1.7	3.4	1 1.00	1	0.9	1.7	1 1.00
					1	2.6	3.7	1 1.00	1	0.9	1.2	1 1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: CARDIOVASCULAR DISORDERS, GENERAL

Adverse events/Assigned treatment	Female				Male				Total				
	No of Pt	% on exp.	% with AE	Ratio of AE	No of Pt	% on exp.	% with AE	Ratio of AE	No of Pt	% on exp.	% with AE	Ratio of AE	
HYPOTENSION AND RELATED SYMPTOMS	15	19.5	27.7	20	1.33	5	13.2	18.5	5	1.00	20	17.4	24.6
	1	1.9	3.4	1	1.00	5	8.6	17.2	5	1.00	6	5.4	10.3
	6	8.6	13.6	7	1.16	4	9.5	14.8	5	1.25	10	8.9	14.0
FLUSHING / HOT FLUSHES	2	2.6	3.7	2	1.00	1	2.6	3.7	2	2.00	3	2.6	3.7
	1	1.9	3.4	1	1.00						1	0.9	1.7
	2	2.9	4.5	2	1.00	1	2.4	3.7	1	1.00	3	2.7	4.2
TACHYCARDIA	4	5.2	7.4	4	1.00						4	3.5	4.9
	2	2.9	4.5	2	1.00	1	2.4	3.7	1	1.00	3	2.7	4.2
	1	1.3	1.8	1	1.00	1	2.6	3.7	1	1.00	2	1.7	2.4
PALPITATION						1	1.7	3.4	1	1.00	1	0.9	1.7
	1	1.4	2.2	1	1.00						1	0.9	1.4
	2	2.6	3.7	2	1.00						2	1.7	2.4
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	1	1.9	3.4	1	1.00						1	0.9	1.7
	1	1.3	1.8	1	1.00						1	0.9	1.2
						1	2.4	3.7	1	1.00	1	0.9	1.4
BRADYCARDIA	1	1.9	3.4	1	1.00						1	0.9	1.7
	1	1.3	1.8	1	1.00						1	0.9	1.2
	1	1.4	2.2	1	1.00						1	0.9	1.4
EXTRASISTOLES													
HAEMORRHIDS THROMBOSED	1	1.4	2.2	1	1.00						1	0.9	1.4

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt	% on exp.	% with AE	Ratio No of AE	No of Pt	% on exp.	% with AE	Ratio No of AE	No of Pt	% on exp.	% with AE	Ratio No of AE
HEADACHE / MIGRAINE	7	9.1	12.9	7 1.00	2	5.3	7.4	2 1.00	9	7.8	11.1	9 1.00
	3	5.6	10.3	4 1.33	6	10.3	20.6	6 1.00	9	8.0	15.5	10 1.11
	10	14.3	22.7	14 1.40	5	11.9	18.5	5 1.00	15	13.4	21.1	19 1.26
TREMOR	16	20.8	29.6	16 1.00	4	10.5	14.8	4 1.00	20	17.4	24.6	20 1.00
	2	3.7	6.8	2 1.00	3	5.2	10.3	3 1.00	5	4.5	8.6	5 1.00
	4	5.7	9.0	4 1.00	2	4.8	7.4	2 1.00	6	5.4	8.4	6 1.00
VERTIGO	7	9.1	12.9	8 1.14					7	6.1	8.6	8 1.14
	4	5.7	9.0	4 1.00	1	2.4	3.7	1 1.00	5	4.5	7.0	5 1.00
	5	6.5	9.2	5 1.00	1	2.6	3.7	1 1.00	6	5.2	7.4	6 1.00
PARESTHESIA	1	1.9	3.4	1 1.00	1	1.7	3.4	1 1.00	2	1.8	3.4	2 1.00
	1	1.4	2.2	1 1.00	1	2.4	3.7	1 1.00	2	1.8	2.8	2 1.00
	2	2.6	3.7	2 1.00					2	1.7	2.4	2 1.00
CONFUSION					1	2.4	3.7	1 1.00	1	0.9	1.4	1 1.00
	1	1.3	1.8	1 1.00					1	0.9	1.2	1 1.00
	1	1.9	3.4	1 1.00	1	1.7	3.4	1 1.00	2	1.8	3.4	2 1.00
MUSCLE CONTRACTIONS INVOLUNTARY					2	5.3	7.4	2 1.00	2	1.7	2.4	2 1.00
	1	1.4	2.2	1 1.00					1	0.9	1.4	1 1.00
	1	1.9	3.4	1 1.00					1	0.9	1.7	1 1.00
HYPERTONIA	1	1.3	1.8	1 1.00					1	0.9	1.2	1 1.00
SPEECH DISORDER												
	1	1.3	1.8	1 1.00					1	0.9	1.2	1 1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: GASTRO-INTESTINAL SYSTEM DISORDERS

Adverse events/Assigned treatment	Female					Male					Total				
	No of Pt	% on exp.	Z on exp.	No of AE	Ratio (%)	No of Pt	% on exp.	Z on exp.	No of AE	Ratio (%)	No of Pt	% on exp.	Z on exp.	No of AE	Ratio (%)
CONSTIPATION	14	18.2	25.9	14	1.00	4	10.5	14.8	4	1.00	18	15.7	22.2	18	1.00
	5	9.3	17.2	5	1.00	1	1.7	3.4	1	1.00	6	5.4	10.3	6	1.00
	12	17.1	27.2	14	1.16	5	11.9	18.5	6	1.20	17	15.2	23.9	20	1.17
NAUSEA AND RELATED SYMPTOMS	13	16.9	24.0	17	1.30	4	10.5	14.8	5	1.25	17	14.8	20.9	22	1.29
	9	16.7	31.0	15	1.66	1	1.7	3.4	1	1.00	10	8.9	17.2	16	1.60
	7	10.0	15.9	7	1.00	3	7.1	11.1	4	1.33	10	8.9	14.0	11	1.10
ABDOMINAL PAIN	3	3.9	5.5	4	1.33	1	2.6	3.7	1	1.00	4	3.5	4.9	5	1.25
	2	3.7	6.8	2	1.00	1	1.7	3.4	1	1.00	3	2.7	5.1	3	1.00
	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
APPETITE INCREASED	2	2.6	3.7	2	1.00						2	1.7	2.4	2	1.00
	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
	1	1.9	3.4	1	1.00	2	3.4	6.8	2	1.00	3	2.7	5.1	3	1.00
DIARRHOEA	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
FLATULENCE	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
	1	1.4	2.2	1	1.00	1	2.6	3.7	1	1.00	1	0.9	1.2	1	1.00
ANOREXIA															
COLITIS															
DUODENAL ULCER REACTIVATED	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
DYSPHAGIA															
GASTROENTERITIS	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
TONGUE ULCERATION															

(CONTINUED)

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: GASTRO-INTESTINAL SYSTEM DISORDERS

Adverse events/Assigned treatment	Female			Male			Total		
	No of Pt	% on exp.	Ratio of AE (*)	No of Pt	% on exp.	Ratio of AE (*)	No of Pt	% on exp.	Ratio of AE (*)
TOOTH DISORDER	1	1.4	1.00	0	0.0	0.00	1	0.9	1.00
Reboxetine	1	2.2	1.00	0	0.0	0.00	1	1.4	1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY
BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: HEARING AND VESTIBULAR DISORDERS

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt	% on exp.	No of Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	No of Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	No of Pt with AE	Ratio No of AE (*)
TINNITUS Imipramine	1	1.3	1.8	1.00	1	2.6	3.7	1.00	2	1.7	2.4	1.00

(*) number of adverse events on patients who complained of adverse events
(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: HEMATOLOGY DISORDERS

Adverse events/Assigned treatment	Female			Total		
	No of Pt	% on exp.	Ratio with AE	No of Pt	% on exp.	Ratio with AE
ANEMIA	1	1.3	1.00	1	0.9	1.00
EOSINOPHILIA	1	1.3	1.00	1	0.9	1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: METABOLIC AND NUTRITIONAL DISORDERS

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)
WEIGHT INCREASE	2	2.6	3.7	2 1.00					2	1.7	2.4	2 1.00
	1	1.4	2.2	1 1.00					1	0.9	1.4	1 1.00
WEIGHT DECREASE					1	1.7	3.4	1 1.00	1	0.9	1.7	1 1.00
	1	1.4	2.2	1 1.00					1	0.9	1.4	1 1.00
HYPERTRIGLYCERIDA - EMIA	1	1.3	1.8	1 1.00					1	0.9	1.2	1 1.00
					1	2.4	3.7	1 1.00	1	0.9	1.4	1 1.00
HYPERURICAEMIA	1	1.3	1.8	1 1.00					1	0.9	1.2	1 1.00
									1	0.9	1.2	1 1.00
PHOSPHATASE ALKALINE INCREASED	1	1.3	1.8	1 1.00					1	0.9	1.2	1 1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 2012A/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY
BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: MUSCULO-SKELETAL SYSTEM DISORDERS

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)
MYALGIA					1	2.6	3.7	1.00	1	0.9	1.2	1.00
					2	3.4	6.8	1.00	2	1.8	3.4	1.00
ARTHRALGIA	1	1.9	3.4	1.00					1	0.9	1.7	1.00
					1	2.4	3.7	1.00	1	0.9	1.4	1.00
BACK PAIN	2	3.7	6.8	1.00					2	1.8	3.4	1.00

268

(*) number of adverse events on patients who complained of adverse events
(some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: PSYCHIATRIC DISORDERS

Adverse events/Assigned treatment	Female					Male					Total				
	No of Pt exp.	% on exp.	No of Pt with AE	No of AE	Ratio (*)	No of Pt exp.	% on exp.	No of Pt with AE	No of AE	Ratio (*)	No of Pt exp.	% on exp.	No of Pt with AE	No of AE	Ratio (*)
AGITATION / ANXIETY / NERVOUSNESS	2	2.6	3.7	2	1.00	3	7.9	11.1	3	1.00	5	4.3	6.1	5	1.00
	4	7.4	13.7	4	1.00	6	10.3	20.6	7	1.16	10	8.9	17.2	11	1.10
	7	10.0	15.9	7	1.00	4	9.5	14.8	6	1.50	11	9.8	15.4	13	1.18
INSOMNIA	6	7.8	11.1	6	1.00	2	5.3	7.4	2	1.00	8	7.0	9.8	8	1.00
	2	3.7	6.8	2	1.00	2	3.4	6.8	2	1.00	4	3.6	6.8	4	1.00
	7	10.0	15.9	7	1.00	5	11.9	18.5	5	1.00	12	10.7	16.9	12	1.00
SOMNOLENCE	4	5.2	7.4	4	1.00	2	5.3	7.4	2	1.00	6	5.2	7.4	6	1.00
	4	7.4	13.7	5	1.25	5	8.6	17.2	5	1.00	9	8.0	15.5	10	1.11
	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
SUICIDE ATTEMPT	2	2.6	3.7	2	1.00	2	5.3	7.4	2	1.00	4	3.5	4.9	4	1.00
	3	5.6	10.3	3	1.00	1	1.7	3.4	1	1.00	4	3.6	6.8	4	1.00
	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00
AUTOLESIONIST BEHAVIOUR	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
CONCENTRATION IMPAIRED	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
DEPERSONALIZATION	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
LIBIDO DECREASED	1	1.9	3.4	1	1.00	1	2.4	3.7	1	1.00	1	0.9	1.4	1	1.00
	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
PARONYCHIA	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY
BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: REPRODUCTIVE DISORDERS, MALE

Adverse events/Assigned treatment		Male				Total			
		No of Pt	Z on exp.	No of Pt with AE	Ratio of AE (*)	No of Pt	Z on exp.	No of Pt with AE	Ratio of AE (*)
EPIDIDYMITIS	Reboxetine	1	2.4	3.7	1.00	1	0.9	1.4	1.00
IMPOTENCE	Reboxetine	1	2.4	3.7	1.00	1	0.9	1.4	1.00
PERINEAL PAIN MALE	Reboxetine	1	2.4	3.7	1.00	1	0.9	1.4	1.00

(*) number of adverse events on patients who complained of adverse events
(some adverse events are grouped in cluster)

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REBOXYTINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY
BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: RESISTANCE MECHANISM DISORDERS

Adverse events/Assigned treatment	Female			Total		
	No of Pt	% on exp.	Ratio No of AE with AE (*)	No of Pt	% on exp.	Ratio No of AE with AE (*)
HERPES SIMPLEX	1	1.9	3.4	1	0.9	1.7
						1.00

(*) number of adverse events on patients who complained of adverse events
(some adverse events are grouped in cluster)

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE NO. 1 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY
BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: RESPIRATORY SYSTEM DISORDERS

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)
RHINITIS	2	2.6	3.7	2 1.00					2	1.7	2.4	2 1.00
					4	6.9	13.7	4 1.00	4	3.6	6.8	4 1.00
	1	1.4	2.2	1 1.00					1	0.9	1.4	1 1.00
DYSPNOEA	2	2.6	3.7	2 1.00					2	1.7	2.4	2 1.00
	3	4.3	6.8	5 1.66					3	2.7	4.2	5 1.66
					1	1.7	3.4	1 1.00	1	0.9	1.7	1 1.00
SINUSITIS	2	2.9	4.5	2 1.00					2	1.8	2.8	2 1.00
	1	1.9	3.4	1 1.00					1	0.9	1.7	1 1.00
					1	1.7	3.4	1 1.00	1	0.9	1.7	1 1.00
BRONCHITIS												
PHARYNGITIS												

(*) number of adverse events on patients who complained of adverse events
(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY
BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: SKIN AND APPENDAGES DISORDERS

Adverse events/Assigned treatment	Female				Male				Total				
	No of Pt	% on exp.	% on Pt with AE	No of AE	No of Pt	% on exp.	% on Pt with AE	No of AE	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
ERYTHEMA / RASH	1	1.3	1.8	1	1.00				1	0.9	1.2	1	1.00
	2	3.7	6.8	2	1.00				2	1.8	3.4	2	1.00
	1	1.4	2.2	1	1.00				1	0.9	1.4	1	1.00
COLD URTICARIA									1	2.6	3.7	1	1.00
RHAGADES	1	1.3	1.8	1	1.00				1	0.9	1.2	1	1.00

273

(*) number of adverse events on patients who complained of adverse events
(some adverse events are grouped in cluster)

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PHARMACIA CNS RED

REBEXETINE - PROTOCOL 20124/015
TABLE No. I 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY
BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: SPECIAL SENSES OTHER, DISORDERS

Adverse events/Assigned treatment	Female			Total		
	No of Pt exp.	No of Pt with AE	Ratio (%)	No of Pt exp.	No of Pt with AE	Ratio (%)
TASTE LOSS	1	1.8	1.00	1	1.2	1.00
TASTE PERVERSION	1	3.4	1.00	1	1.7	1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: URINARY SYSTEM DISORDERS

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)
URINARY HESITANCY / RETENTION	1	1.3	1.8	1.00					1	0.9	1.2	1.00
	1	1.9	3.4	1.00	1	1.7	3.4	1.00	2	1.8	3.4	1.00
					6	14.3	22.2	1.00	6	5.4	8.4	1.00
URINARY TRACT INFECTION	1	1.9	3.4	1.00					1	0.9	1.7	1.00
	4	5.7	9.0	1.00					4	3.6	5.6	1.00
DYSURIA					1	2.6	3.7	1.00	1	0.9	1.2	1.00
					2	4.8	7.4	1.00	2	1.8	2.8	1.00
MICTURITION FREQUENCY					1	1.7	3.4	1.00	1	0.9	1.7	1.00
	1	1.4	2.2	1.00					1	0.9	1.4	1.00
PYURIA												

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015
TABLE NO.: 46

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT, BODY SYSTEM AND SEX

Body system: VISION DISORDERS

Adverse events/Assigned treatment	Female				Male				Total			
	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)	No of Pt	% on exp.	% on Pt with AE	Ratio No of AE (*)
BLURRED VISION	7	9.1	12.9	3 1.14	3	7.9	11.1	3 1.00	10	8.7	12.3	11 1.10
CONJUNCTIVITIS	3	4.3	6.8	3 1.00	3	5.2	10.3	3 1.00	3	2.7	5.1	3 1.00
	2	2.6	3.7	2 1.00	3	7.1	11.1	4 1.33	6	5.4	8.4	7 1.16
HYDRIASIS	1	1.4	2.2	1 1.00	1	2.4	3.7	1 1.00	2	1.7	2.4	2 1.00
	1	1.9	3.4	1 1.00					1	0.9	1.7	1 1.00
EYE ABNORMALITY	1	1.4	2.2	1 1.00					1	0.9	1.4	1 1.00

(*) number of adverse events on patients who complained of adverse events (some adverse events are grouped in cluster)

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 47

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX, GROUPED BY BODY SYSTEM

Body system/Assigned treatment	Female					Male					Total					
	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	
Pt exposed	Imipramine	77	100.0			38	100.0				115	100.0				
	Placebo	54	100.0			58	100.0				112	100.0				
	Reboxetine	70	100.0			42	100.0				112	100.0				
Pt with a.e.	Imipramine	54	70.1	100.0	218	4.03	27	71.1	100.0	70	2.59	81	70.4	100.0	288	3.55
	Placebo	29	53.7	100.0	78	2.68	29	50.0	100.0	63	2.17	58	51.8	100.0	141	2.49
	Reboxetine	44	62.9	100.0	136	3.09	27	64.3	100.0	75	2.77	71	63.4	100.0	211	2.97
AUTONOMIC NERVOUS SYSTEM DISORDERS	Imipramine	39	50.6	72.2	58	1.48	17	44.7	62.9	21	1.23	56	48.7	69.1	79	1.41
	Placebo	12	22.2	41.3	12	1.00	5	8.6	17.2	6	1.20	17	15.2	29.3	18	1.05
	Reboxetine	27	38.6	61.3	32	1.18	13	31.0	48.1	13	1.00	40	35.7	56.3	45	1.12
GASTRO-INTESTINAL SYSTEM DISORDERS	Imipramine	28	36.4	51.8	38	1.35	8	21.1	29.6	12	1.50	36	31.3	44.4	50	1.38
	Placebo	13	24.1	44.8	25	1.92	5	8.6	17.2	6	1.20	18	16.1	31.0	31	1.72
	Reboxetine	19	27.1	43.1	26	1.36	7	16.7	25.9	10	1.42	26	23.2	36.6	36	1.98
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Imipramine	30	39.0	55.5	40	1.33	6	15.8	22.2	9	1.50	36	31.3	44.4	49	1.36
	Placebo	7	13.0	24.1	9	1.28	9	15.5	31.0	11	1.22	16	14.3	27.5	20	1.25
	Reboxetine	18	25.7	40.9	24	1.33	9	21.4	39.3	10	1.11	27	24.1	38.0	34	1.25
PSYCHIATRIC DISORDERS	Imipramine	16	20.8	29.6	18	1.12	9	23.7	39.3	9	1.00	25	21.7	30.8	27	1.08
	Placebo	13	24.1	44.8	16	1.23	11	19.0	37.9	15	1.36	24	21.4	41.3	31	1.29
	Reboxetine	12	17.1	27.2	16	1.33	8	19.0	29.6	12	1.50	20	17.9	28.1	28	1.40
CARDIOVASCULAR DISORDERS, GENERAL	Imipramine	21	27.3	38.8	31	1.47	7	18.4	25.9	8	1.14	28	24.3	34.5	39	1.39
	Placebo	4	7.4	13.7	4	1.00	6	10.3	20.6	6	1.00	10	8.9	17.2	10	1.00
	Reboxetine	9	12.9	20.4	13	1.44	7	16.7	25.9	8	1.14	16	14.3	22.5	21	1.31
VISION DISORDERS	Imipramine	9	11.7	16.6	10	1.11	3	7.9	11.1	3	1.00	12	10.4	14.8	13	1.08

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(*) number of adverse events on patients who complained of adverse events

277

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 47

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX, GROUPED BY BODY SYSTEM

Body system/assigned treatment	Female						Male						Total					
	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)			
VISION DISORDERS	Placebo	1	1.9	3.4	1	1.00	3	5.2	10.3	3	1.00	4	3.6	6.8	4	1.00		
	Reboxetine	5	7.1	11.3	5	1.00	4	9.5	14.8	5	1.25	9	8.0	12.6	10	1.11		
	Imipramine	5	6.5	9.2	6	1.20	4	10.5	14.8	4	1.00	9	7.8	11.1	10	1.11		
BODY AS A WHOLE-GENERAL DISORDERS	Placebo	1	1.9	3.4	1	1.00	5	8.6	17.2	5	1.00	6	5.4	10.3	6	1.00		
	Reboxetine	4	5.7	9.0	4	1.00	3	7.1	11.1	3	1.00	7	6.3	9.8	7	1.00		
URINARY SYSTEM DISORDERS	Imipramine	1	1.3	1.8	1	1.00	1	2.6	3.7	1	1.00	2	1.7	2.4	2	1.00		
	Placebo	2	3.7	6.8	2	1.00	2	3.4	6.8	2	1.00	4	3.6	6.8	4	1.00		
RESPIRATORY SYSTEM DISORDERS	Reboxetine	5	7.1	11.3	5	1.00	7	16.7	25.9	8	1.14	12	10.7	16.9	13	1.08		
	Imipramine	4	5.2	7.4	4	1.00						4	3.5	4.9	4	1.00		
	Placebo	1	1.9	3.4	1	1.00	6	10.3	20.6	6	1.00	7	6.3	12.0	7	1.00		
METABOLIC AND NUTRITIONAL DISORDERS	Reboxetine	4	5.7	9.0	8	2.00						4	3.6	5.6	8	2.00		
	Imipramine	5	6.5	9.2	5	1.00						5	4.3	6.1	5	1.00		
	Placebo						1	1.7	3.4	1	1.00	1	0.9	1.7	1	1.00		
MUSCULO-SKELETAL SYSTEM DISORDERS	Reboxetine	1	1.4	2.2	2	2.00	1	2.4	3.7	1	1.00	2	1.8	2.8	3	1.50		
	Imipramine						1	2.6	3.7	1	1.00	1	0.9	1.2	1	1.00		
	Placebo	3	5.6	10.3	3	1.00	2	3.4	6.8	2	1.00	5	4.5	8.6	5	1.00		
SKIN AND APPENDAGES DISORDERS	Reboxetine						1	2.4	3.7	1	1.00	1	0.9	1.4	1	1.00		
	Imipramine	2	2.6	3.7	2	1.00	1	2.6	3.7	1	1.00	3	2.6	3.7	3	1.00		
	Placebo	2	3.7	6.8	2	1.00						2	1.8	3.4	2	1.00		
HEARING AND VESTIBULAR DISORDERS	Reboxetine	1	1.4	2.2	1	1.00						1	0.9	1.4	1	1.00		
	Imipramine	1	1.3	1.8	1	1.00	1	2.6	3.7	1	1.00	2	1.7	2.4	2	1.00		

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(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 47

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATMENT AND SEX, GROUPED BY BODY SYSTEM

Body system/Assigned treatment	Female					Male					Total				
	No of Pt	% on exp.	No of Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	No of Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	No of Pt with AE	No of AE	Ratio (*)
HEMATOLOGY DISORDERS	2	2.6	3.7	2	1.00						2	1.7	2.4	2	1.00
LIVER AND BILIAR SYSTEM DISORDERS	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
						1	2.4	3.7	1	1.00	1	0.9	1.4	1	1.00
REPRODUCTIVE DISORDERS, MALE						2	4.8	7.4	3	1.50	2	1.8	2.8	3	1.50
SPECIAL SENSES OTHER, DISORDERS	1	1.3	1.8	1	1.00						1	0.9	1.2	1	1.00
	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00
RESISTANCE MECHANISM DISORDERS	1	1.9	3.4	1	1.00						1	0.9	1.7	1	1.00

(*) number of adverse events on patients who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Total	Days of treatment																				
			0-7			8-14			15-21			22-28			29-35			36-42			> 42		
			No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%
MOUTH DRY	Imipramine	53	100	33	62.3	8	15.1	6	11.3	4	7.5	2	3.8										
	Placebo	15	100	8	53.3	2	13.3	2	13.3	3	20.0												
	Reboxetine	29	100	17	58.6	9	31.0	2	6.9														
CONSTIPATION	Imipramine	18	100	5	27.8	7	38.9	3	16.7														
	Placebo	6	100	1	16.7	3	50.0	1	16.7														
	Reboxetine	20	100	7	35.0	8	40.0	1	5.0	3	15.0	1	5.0										
SWEATING INCREASED	Imipramine	26	100	15	57.7	3	11.5	1	3.8	4	15.4	1	3.8	1	3.8	1	3.8	1	3.8	1	3.8	1	3.8
	Placebo	3	100	2	66.7	1	33.3																
	Reboxetine	15	100	7	46.7	6	40.0	1	6.7	1	6.7												
TREMOR	Imipramine	20	100	6	30.0	6	30.0	5	25.0	1	5.0	2	10.0										
	Placebo	5	100	4	80.0																		
	Reboxetine	6	100	4	66.7	1	16.7																
HEADACHE	Imipramine	9	100	4	44.4	1	11.1	2	22.2	2	22.2												
	Placebo	10	100	3	30.0	2	20.0	3	30.0	1	10.0												
	Reboxetine	18	100	10	55.6	3	16.7																
NAUSEA	Imipramine	16	100	6	37.5	3	18.8	4	25.0														
	Placebo	11	100	3	27.3	3	27.3	2	18.2	1	9.1												
	Reboxetine	9	100	6	66.7																		
INSOMNIA	Imipramine	8	100	4	50.0	1	12.5	1	12.5														
	Placebo	4	100	2	50.0																		
	Reboxetine	12	100	6	50.0	2	16.7	3	25.0														
VISION ABNORMAL	Imipramine	10	100	3	30.0	4	40.0	1	10.0														
	Reboxetine																						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Total	Days of treatment														
			0-7		8-14		15-21		22-28		29-35		36-42		> 42		
			No	%	No	%	No	%	No	%	No	%	No	%	No	%	
VISION ABNORMAL	Placebo	3	100														
	Reboxetine	7	100	3	42.9	1	14.3	1	14.3	2	28.6						
DIZZINESS	Imipramine	16	100	6	37.5	4	25.0	2	12.5	1	6.3	1	6.3	2	12.5		
	Placebo	4	100	1	25.0			2	50.0					1	25.0		
SOMNOLENCE	Reboxetine	8	100	2	25.0					2	25.0			2	25.0		
	Imipramine	6	100	6	100												
	Placebo	10	100	3	30.0	1	10.0					3	30.0	2	20.0	1	10.0
	Reboxetine	1	100					1	100								
AGITATION	Imipramine	4	100	3	75.0	1	25.0										
	Placebo	7	100	4	57.1	2	28.6			1	14.3						
	Reboxetine	8	100	2	25.0	3	37.5	2	25.0			2	25.0			1	12.5
	Imipramine	4	100					1	25.0	1	25.0	1	25.0	2	50.0		
FATIGUE	Placebo	4	100			3	75.0			1	25.0						
	Reboxetine	3	100	1	33.3	1	33.3	1	33.3								
VERTIGO	Imipramine	8	100	5	62.5			1	12.5			2	25.0				
	Reboxetine	5	100	3	60.0	2	40.0										
ABDOMINAL PAIN	Imipramine	5	100	2	40.0	2	40.0	1	20.0								
	Placebo	3	100	1	33.3	2	66.7										
	Reboxetine	1	100					1	100								
	Imipramine	1	100	1	100												
HICTURITION DISORDER	Placebo	1	100	1	100												
	Reboxetine	3	100	1	33.3			1	33.3	1	33.3	1	33.3				

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PHARMACIA CMS RRD

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Total	Days of treatment														
			0-7		8-14		15-21		22-28		29-35		36-42		> 42		
			No	%	No	%	No	%	No	%	No	%	No	%	No	%	
HOT FLUSHES	Imipramine	4	100	1	25.0	1	25.0	1	25.0								
	Placebo	1	100							1	100						
	Reboxetine	2	100			1	50.0	1	50.0								
PARAESTHESIA	Imipramine	6	100	4	66.7	1	16.7										
	Placebo	2	100	1	50.0			1	50.0								
	Reboxetine	2	100	2	100												
RHINITIS	Imipramine	2	100	1	50.0			1	50.0								
	Placebo	4	100	1	25.0	1	25.0	2	50.0								
	Reboxetine	1	100	1	100												
HYPOTENSION POSTURAL	Imipramine	6	100	4	66.7					1	16.7			1	16.7		
	Reboxetine	2	100	1	50.0					1	50.0						
	Imipramine	2	100	1	50.0					1	50.0						
WEIGHT INCREASE	Imipramine	1	100	1	100												
	Reboxetine	2	100	2	100												
	Placebo	1	100	1	100												
DYSPEPSIA	Imipramine	5	100	1	20.0	1	20.0	2	40.0							1	20.0
	Placebo	1	100	1	100												
	Placebo	1	100	1	100												
URINARY RETENTION	Reboxetine	3	100	3	100												
	Placebo	1	100														
	Placebo	1	100														
NERVOUSNESS	Reboxetine	4	100	2	50.0	2	50.0										
	Imipramine	3	100	2	66.7			1	33.3								
	Imipramine	3	100	2	66.7			1	33.3								

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Total	Days of treatment														
			0-7		8-14		15-21		22-28		29-35		36-42		> 42		
			No	%	No	%	No	%	No	%	No	%	No	%	No	%	
ASTHENIA	Reboxetine	1	100														
	Imipramine	4	100	2	50.0	1	25.0	1	25.0								
	Reboxetine	3	100	2	66.7			1	33.3								
URINARY TRACT INFECTION	Placebo	1	100														
	Reboxetine	4	100			3	75.0										
	Imipramine	2	100	1	50.0	1	50.0										
PALPITATION	Placebo	1	100			1	100										
	Reboxetine	1	100	1	100												
	Imipramine	4	100	2	50.0							1	25.0	1	25.0		
SUICIDE ATTEMPT	Placebo	4	100			1	25.0			2	50.0			1	25.0		
	Reboxetine	1	100	1	100												
	Imipramine	1	100									1	100				
HYPOTENSION	Placebo	2	100	1	50.0							1	50.0				
	Reboxetine	2	100	1	50.0							1	50.0				
	Imipramine	2	100	2	100												
DYSPNOEA	Reboxetine	5	100									2	40.0	2	40.0	1	20.0
	Placebo	1	100									1	100				
	Reboxetine	1	100														
HYPERKINESIA	Imipramine	1	100	1	100												
	Placebo	2	100	1	50.0							1	50.0				
	Reboxetine	1	100	1	100												
FLATULENCE	Placebo	1	100														
	Reboxetine	1	100														
	Imipramine	1	100	1	100												
HYPERTENSION	Placebo	1	100	1	100												
	Imipramine	1	100	1	100												
	Reboxetine	1	100	1	100												

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 2012/4/015
TABLE No. : 46

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Total	Days of treatment																				
			0-7			8-14			15-21			22-28			29-35			36-42			> 42		
			No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%
VOMITING	Imipramine	1	100																				
	Placebo	4	100	2	50.0	1	25.0	1	25.0														
	Reboxetine	1	100	1	100																		
SLEEP DISORDER	Imipramine	1	100																				
	Placebo	1	100																				
	Reboxetine	1	100	1	100																		
SINUSITIS	Imipramine	1	100																				
	Placebo	1	100																				
	Reboxetine	1	100	1	100																		
MUSCLE CONTRACTIONS INVOLUNTARY	Imipramine	2	100																				
	Placebo	2	100																				
	Reboxetine	1	100																				
RASH	Imipramine	1	100																				
	Placebo	2	100																				
	Reboxetine	1	100																				
ANXIETY	Imipramine	1	100																				
	Placebo	2	100																				
	Reboxetine	3	100	3	100																		
PERINEAL PAIN MALE	Imipramine	1	100																				
	Placebo	1	100																				
	Reboxetine	1	100	1	100																		
NYALCIA	Imipramine	1	100																				
	Placebo	2	100	2	100																		
	Reboxetine	2	100	1	50.0	1	50.0																
CONFUSION	Imipramine	1	100																				
	Placebo	2	100	1	50.0	1	50.0																
	Reboxetine	2	100	1	50.0	1	50.0																
CONJUNCTIVITIS	Imipramine	2	100	1	50.0	1	50.0																
	Placebo	2	100	1	50.0	1	50.0																
	Reboxetine	2	100	1	50.0	1	50.0																

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 48

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Total	Days of treatment																				
			0-7			8-14			15-21			22-28			29-35			36-42			> 42		
			No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%	No	AE	%
CHEST PAIN PRECORDIAL	Placebo	1	100																				
DIARRHOEA	Placebo	3	100	3	100																		
IMPOTENCE	Reboxetine	1	100	1	100																		
EPIDIDYMITIS	Reboxetine	1	100	1	100																		
BACK PAIN	Placebo	2	100			1	50.0			1	50.0			1	50.0								
TINNITUS	Imipramine	2	100	1	50.0			1	50.0														
TASTE LOSS	Imipramine	1	100	1	100																		
DYSURIA	Imipramine	1	100	1	100																		
	Reboxetine	2	100	2	100																		
ARTHRALGIA	Placebo	1	100	1	100																		
	Reboxetine	1	100																				
ANOREXIA	Reboxetine	1	100	1	100																		
HYDRIASIS	Reboxetine	2	100	1	50.0			1	50.0														
BRAGADES	Imipramine	1	100					1	100														
CONCENTRATION IMPAIRED	Imipramine	1	100											1	100								
INFLUENZA-LIKE SYMPTOMS	Imipramine	1	100											1	100								
	Placebo	1	100											1	100								
	Reboxetine	1	100																				
HYPERURICAEMIA	Reboxetine	1	100											1	100								
DYSFHAGIA	Imipramine	1	100	1	100																		
SALIVA INCREASED	Reboxetine	1	100	1	100																		

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 46

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Total	Days of treatment														
			0-7		8-14		15-21		22-28		29-35		36-42		> 42		
			No	%	No	%	No	%	No	%	No	%	No	%	No	%	
ADVERSE EVENTS																	
DUODENAL ULCER REACTIVATED	Imipramine	1	100														
GAMMA-GT INCREASED	Imipramine	1	100														
	Reboxetine	1	100			1	100									1	100
SPEECH DISORDER	Imipramine	1	100														
	Placebo	1	100														
HYPERTONIA	Imipramine	1	100														
DEPERSONALIZATION	Imipramine	1	100	1	100												
SYNCOPE	Imipramine	2	100	1	50.0												
	Imipramine	1	100	1	100												
CHEST PAIN	Reboxetine	1	100	1	100												
MICTURITION FREQUENCY	Placebo	1	100	1	100												
EYE ABNORMALITY	Reboxetine	1	100	1	100												
TOOTH DISORDER	Reboxetine	1	100	1	100												
COLD URTICARIA	Imipramine	1	100														
	Imipramine	1	100														
PHARYNGITIS	Placebo	1	100														
FLUSHING	Reboxetine	1	100														
HAEMORRHOIDS THROBOSSED	Reboxetine	1	100														
TONGUE ULCERATION	Placebo	1	100														
	Reboxetine	1	100														
LIBIDO DECREASED	Placebo	1	100														
	Reboxetine	1	100														
TASTE PERVERSION	Placebo	1	100														
	Reboxetine	1	100														
PARONIMIA	Placebo	1	100														
	Reboxetine	1	100														

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 48

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Total	Days of treatment														
			0-7		8-14		15-21		22-28		29-35		36-42		> 42		
			No	%	No	%	No	%	No	%	No	%	No	%	No	%	
ACCOMMODATION ABNORMAL	Imipramine	1	100														
AUTOLESIONIST BEHAVIOUR	Imipramine	1	100	1	100												
MIGRAINE	Reboxetine	1	100	1	100												
HYPERPREXIA	Reboxetine	1	100	1	100												
COLITIS	Imipramine	1	100			1	100										
EXTRASYSTOLES	Imipramine	1	100			1	100										
BRADYCARDIA	Placebo	1	100			1	100										
CHROMATOPSIA	Placebo	1	100			1	100										
MALAISE	Placebo	1	100			1	100										
HYPOKALAEMIA	Imipramine	1	100							1	100						
DEPRESSION AGGRAVATED	Placebo	1	100							1	100						
GASTRITIS	Reboxetine	1	100							1	100						
PYURIA	Reboxetine	1	100							1	100						
GASTROENTERITIS	Reboxetine	1	100									1	100				
PHOSPHATASE ALKALINE INCREASED	Imipramine	1	100											1	100		
ANAEMIA HYPOCHROMIC	Imipramine	1	100											1	100		
EOSINOPHILIA	Imipramine	1	100											1	100		
BRONCHITIS	Placebo	1	100											1	100		
HERPES SIMPLEX	Placebo	1	100											1	100		
RASH ERYTHEMATOUS	Reboxetine	1	100											1	100		
HYPERTRIGLYCERIDAEMIA	Imipramine	1	100													1	100

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. 1 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: AUTONOMIC NERVOUS SYSTEM DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
	No AE	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
MOUTH DRY	53	100	33	62.3	8	15.1	6	11.3	4	7.5	2	3.8				
	15	100	8	53.3	2	13.3	2	13.3	3	20.0						
	29	100	17	58.6	9	31.0	2	6.9					1	3.4		
SWEATING INCREASED	26	100	15	57.7	3	11.5	1	3.8	4	15.4	1	3.8	1	3.8	1	3.8
	3	100	2	66.7	1	33.3										
	15	100	7	46.7	6	40.0	1	6.7	1	6.7						
SALIVA INCREASED	1	100	1	100												

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(some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: BODY AS A WHOLE-GENERAL DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
	No AE	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
ASTHENIA / FATIGUE	Imipramine	7	100	2	28.6			2	28.6	1	14.3	2	28.6			
	Placebo	4	100			3	75.0	1	25.0							
	Reboxetine	4	100	2	50.0	1	25.0	1	25.0							
INFLUENZA-LIKE SYMPTOMS	Imipramine	1	100							1	100					
	Placebo	1	100						1	100						
CHEST PAIN	Imipramine	1	100											1	100	
	Reboxetine	1	100	1	100											
RIGORS	Imipramine	1	100													
	Reboxetine	1	100	1	100											
HYPERPYREXIA	Imipramine	1	100													
	Reboxetine	1	100	1	100											
MALAISE	Imipramine	1	100													
	Placebo	1	100			1	100									

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: CARDIOVASCULAR DISORDERS, GENERAL

Adverse events/Assigned treatment	Total		Days of treatment													
	No AE	Z	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No AE	Z	No AE	Z	No AE	Z	No AE	Z	No AE	Z	No AE	Z	No AE	Z
HYPOTENSION AND RELATED SYMPTOMS	25	100	11	44.0	6	24.0	2	8.0	2	8.0	1	4.0	3	12.0		
	6	100	2	33.3			2	33.3	1	16.7	1	16.7				
	12	100	4	33.3	2	16.7			4	33.3	2	16.7				
FLUSHING / HOT FLUSHES	4	100	1	25.0	1	25.0	1	25.0								
	1	100														
	3	100			2	66.7	1	33.3								
TACHYCARDIA	4	100	2	50.0	1	25.0	1	25.0								
	3	100	2	66.7			1	33.3								
	2	100	1	50.0			1	50.0								
PALPITATION	1	100														
	1	100	1	100												
	1	100	1	100												
HYPERTENSION	1	100	1	100												
	1	100	1	100												
	1	100	1	100												
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	2	100	1	50.0	1	50.0										
	1	100			1	100										
	1	100			1	100										
HAEMORRHOIDS THROMBOSED	1	100														
	1	100			1	100										
	1	100					1	100								
EXTRASYSTOLES	1	100														
	1	100														
	1	100														
BRADYCARDIA	1	100														
	1	100														
	1	100														

(Some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO

Adverse events/Assigned treatment	Total		Days of treatment														
	No AE	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42		
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	
TREMOR	Imipramine	20	100	6	30.0	6	30.0	5	25.0	1	5.0	2	10.0				
	Placebo	5	100	4	80.0							1	20.0				
	Reboxetine	6	100	4	66.7	1	16.7			1	16.7						
HEADACHE / MIGRAINE	Imipramine	9	100	4	44.4	1	11.1	2	22.2	2	22.2						
	Placebo	10	100	3	30.0	2	20.0	3	30.0	1	10.0	1	10.0				
	Reboxetine	19	100	11	57.9	3	15.8			3	15.8	1	5.3	1	5.3		
VERTIGO	Imipramine	8	100	5	62.5			1	12.5	2	25.0						
	Reboxetine	5	100	3	60.0	2	40.0										
	Imipramine	6	100	4	66.7	1	16.7			1	16.7						
PARAESTHESIA	Placebo	2	100	1	50.0			1	50.0								
	Reboxetine	2	100	2	100												
	Imipramine	1	100	1	100												
MUSCLE CONTRACTIONS INVOLUNTARY	Placebo	2	100	1	50.0	1	50.0			1	50.0	1	50.0				
	Imipramine	2	100					1	50.0	1	50.0						
	Reboxetine	1	100					1	100								
CONFUSION	Imipramine	2	100	1	50.0	1	50.0										
	Reboxetine	1	100	1	100												
	Imipramine	1	100											1	100		
HYPERTONIA	Imipramine	1	100											1	100		
	Placebo	1	100											1	100		

(some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: GASTRO-INTESTINAL SYSTEM DISORDERS

Adverse events/Assigned treatment	Total	Days of treatment															
		0-7		8-14		15-21		22-28		29-35		36-42		> 42			
		No	%	No	%	No	%	No	%	No	%	No	%	No	%		
CONSTIPATION	Imipramine	18	100	5	27.8	7	38.9	3	16.7			2	11.1	1	5.6		
	Placebo	6	100	1	16.7	3	50.0	1	16.7			1	16.7				
	Reboxetine	20	100	7	35.0	8	40.0	1	5.0	3	15.0	1	5.0				
NAUSEA AND RELATED SYMPTOMS	Imipramine	22	100	8	36.4	4	18.2	6	27.3					3	13.6	1	4.5
	Placebo	16	100	6	37.5	4	25.0	3	18.8	1	6.3	2	12.5				
	Reboxetine	11	100	7	63.6			2	18.2	2	18.2						
ABDOMINAL PAIN	Imipramine	5	100	2	40.0	2	40.0	1	20.0								
	Placebo	3	100	1	33.3	2	66.7										
	Reboxetine	1	100					1	100								
APPETITE INCREASED	Imipramine	2	100	2	100												
	Placebo	1	100	1	100												
	Placebo	1	100			1	100										
FLATULENCE	Reboxetine	1	100														
	Placebo	1	100														
	Reboxetine	1	100														
DIARRHOEA	Placebo	3	100	3	100												
	Reboxetine	1	100	1	100												
	Imipramine	1	100	1	100												
DYSPHAGIA	Imipramine	1	100														
	Imipramine	1	100														
	Reboxetine	1	100			1	100										
TOOTH DISORDER	Reboxetine	1	100	1	100												
	Placebo	1	100					1	100								
	Imipramine	1	100							1	100						
TONGUE ULCERATION	Imipramine	1	100														
	Placebo	1	100							1	100						
	Reboxetine	1	100														
GASTROENTERITIS	Reboxetine	1	100											1	100		
	Placebo	1	100														
	Imipramine	1	100														

(some adverse events are grouped in cluster)

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23
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REBOXETINE - PROTOCOL 20124/015
TABLE No. : 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: HEARING AND VESTIBULAR DISORDERS

Adverse events/Assigned treatment	Days of treatment															
	Total		0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
TINNITUS	2	100	1	50.0	1	50.0										
Imipramine																

(some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: HEMATOLOGY DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
	No AE	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
ANEMIA	1	100														
EOSINOPHILIA	1	100												1	100	

294

(some adverse events are grouped in cluster)

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 49

ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM
 Body system: LIVER AND BILIAR SYSTEM DISORDERS

Adverse events/Assigned treatment	Days of treatment															
	Total		0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
INCREASED LIVER ENZYMES	1	100														
Imipramine	1	100														
Reboxetine	1	100					1	100					1	100		

295

(some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 2012A/015
TABLE No.: 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: METABOLIC AND NUTRITIONAL DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
	No	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	AE	Z	No	%	No	%	No	%	No	%	No	%	No	%	No	%
WEIGHT INCREASE	2	100	1	50.0					1	50.0						
Imipramine			1	100												
Reboxetine	1	100														
WEIGHT DECREASE	1	100					1	100								
Placebo							1	100								
Reboxetine	1	100														
Reboxetine	1	100							1	100						
HYPERURICAEMIA	1	100														
Imipramine																
Imipramine	1	100														
Imipramine	1	100												1	100	
Imipramine	1	100														1

296

(some adverse events are grouped in cluster)

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: MUSCULO-SKELETAL SYSTEM DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
	No	AE %	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
MYALGIA	1	100	1	100												
	2	100	2	100												
BACK PAIN	2	100			1	50.0			1	50.0						
ARTHRALGIA	1	100	1	100												
Reboxetine	1	100												1	100	

297

(some adverse events are grouped in cluster)

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: PSYCHIATRIC DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment															
	No AE	%	0-7	8-14	15-21	22-28	29-35	36-42	> 42	0-7	8-14	15-21	22-28	29-35	36-42	> 42		
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
INSOMNIA	Imipramine	8	100	4	50.0	1	12.5	1	12.5					2	25.0			
	Placebo	4	100	2	50.0			1	25.0	1	25.0							
	Reboxetine	12	100	6	50.0	2	16.7	3	25.0							1	8.3	
AGITATION / ANXIETY / NERVOUSNESS	Imipramine	5	100	3	60.0	1	20.0						1	20.0				
	Placebo	11	100	7	63.6	3	27.3			1	9.1							
	Reboxetine	13	100	5	38.5	5	38.5	2	15.4							1	7.7	
SOMNOLENCE	Imipramine	6	100	6	100													
	Placebo	10	100	3	30.0	1	10.0			3	30.0	2	20.0	1	10.0			
	Reboxetine	1	100			1	100											
SUICIDE ATTEMPT	Imipramine	4	100	2	50.0									1	25.0	1	25.0	
	Placebo	4	100			1	25.0	2	50.0					1	25.0			
	Reboxetine	1	100	1	100													
SLEEP DISORDER	Imipramine	1	100	1	100													
CONCENTRATION IMPAIRED	Imipramine	1	100	1	100													
DEPERSONALIZATION	Imipramine	1	100	1	100													
LIBIDO DECREASED	Reboxetine	1	100			1	100											
PARONIRIA	Placebo	1	100										1	100				
AUTOLESIONIST BEHAVIOUR	Imipramine	1	100	1	100													
DEPRESSION AGRAVATED	Placebo	1	100										1	100				

(some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: REPRODUCTIVE DISORDERS, MALE

Adverse events/Assigned treatment	Total		Days of treatment													
	No	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No	%	No	%	No	%	No	%	No	%	No	%	No	%
PERINEAL PAIN MALE	1	100	1	100												
EPIDIDYMITIS	1	100	1	100												
IMPOTENCE	1	100	1	100												

(some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: RESISTANCE MECHANISM DISORDERS

Adverse events/Assigned treatment	Days of treatment															
	Total		0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
HERPES SIMPLEX	1	100														
Placebo																

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(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 49

ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: RESPIRATORY SYSTEM DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment															
			0-7		8-14		15-21		22-28		29-35		36-42		> 42			
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
RHINITIS	Imipramine	2	100	1	50.0			1	50.0									
	Placebo	4	100	1	25.0	1	25.0	2	50.0									
	Reboxetine	1	100	1	100													
DYSPNOEA	Imipramine	2	100	2	100													
	Reboxetine	5	100						2	40.0			2	40.0			1	20.0
SINUSITIS	Placebo	1	100							1	100							
	Reboxetine	2	100							1	50.0		1	50.0				
PHARYNGITIS	Placebo	1	100							1	100							
BRONCHITIS	Placebo	1	100														1	100

(Some adverse events are grouped in cluster)

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PHARMACIA CMS RED

REBOXETINE – PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: SKIN AND APPENDAGES DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
	No AE	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
ERYTHEMA / RASH	Imipramine	1	100								1	100				
	Placebo	2	100												2	100
	Reboxetine	1	100													
PRURITUS	Imipramine	1	100					1	100							
COLD URTICARIA	Imipramine	1	100		1	100										

(some adverse events are grouped in cluster)

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 49

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: SPECIAL SENSES OTHER, DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
	No AE	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
TASTE LOSS	1	100	1	100												
TASTE PERVERSION	1	100							1	100						

303

(Some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: URINARY SYSTEM DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
	No AE	%	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
URINARY HESITANCY / RETENTION	1	100	1	100												
	2	100	2	100												
	6	100	4	66.7			1	16.7	1	16.7						
URINARY TRACT INFECTION	1	100												1	100	
	4	100					3	75.0					1	25.0		
DYSURIA	1	100	1	100												
	2	100	2	100												
MICTURITION FREQUENCY	1	100	1	100												
	1	100							1	100						
PYURIA	1	100														

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 49

ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: VISION DISORDERS

Adverse events/Assigned treatment	Total		Days of treatment													
			0-7		8-14		15-21		22-28		29-35		36-42		> 42	
			No	%	No	%	No	%	No	%	No	%	No	%	No	%
BLURRED VISION	11	100	3	27.3	4	36.4	1	9.1			3	27.3				
	3	100			3	100										
CONJUNCTIVITIS	7	100	3	42.9	1	14.3	1	14.3			2	28.6				
	2	100	1	50.0	1	50.0										
HYDRIASIS	2	100	1	50.0	1	50.0										
	1	100	1	100												
EYE ABNORMALITY	1	100														
	1	100					1	100								
CHROMATOPSIA	1	100														

305

(some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 50

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET
BY ASSIGNED TREATMENT AND GROUPED BY BODY SYSTEM

Body system	Assigned treatment	Total	Days of treatment														
			0-7		8-14		15-21		22-28		29-35		36-42		> 42		
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	
AUTONOMIC NERVOUS SYSTEM DISORDERS	Imipramine	79	100	48	60.8	11	13.9	7	8.9	8	10.1	3	3.8	1	1.3	1	1.3
	Placebo	18	100	10	55.6	3	16.7	2	11.1	3	16.7						
	Reboxetine	45	100	25	55.6	15	33.3	3	6.7	1	2.2			1	2.2		
GASTRO-INTESTINAL SYSTEM DISORDERS	Imipramine	50	100	18	36.0	14	28.0	11	22.0			2	4.0	4	8.0	1	2.0
	Placebo	31	100	12	38.7	10	32.3	5	16.1	1	3.2	3	9.7				
	Reboxetine	36	100	16	44.4	9	25.0	4	11.1	5	13.9	2	5.6				
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Imipramine	49	100	21	42.9	9	18.4	9	18.4	8	16.3	2	4.1				
	Placebo	20	100	9	45.0	3	15.0	4	20.0	2	10.0	2	10.0				
	Reboxetine	34	100	21	61.8	6	17.6	1	2.9	4	11.8	1	2.9	1	2.9		
PSYCHIATRIC DISORDERS	Imipramine	27	100	18	66.7	2	7.4	1	3.7	2	7.4	3	11.1	1	3.7		
	Placebo	31	100	12	38.7	4	12.9	2	6.5	9	29.0	3	9.7	1	3.2		
	Reboxetine	28	100	12	42.9	7	25.0	7	25.0					2	7.1		
CARDIOVASCULAR DISORDERS, GENERAL	Imipramine	39	100	17	43.6	9	23.1	6	15.4	2	5.1	2	5.1	3	7.7		
	Placebo	10	100	2	20.0	1	10.0	4	40.0	1	10.0	2	20.0				
	Reboxetine	21	100	8	38.1	5	23.8	2	9.5	4	19.0	2	9.5				
VISION DISORDERS	Imipramine	13	100	4	30.8	5	38.5	1	7.7			3	23.1				
	Placebo	4	100			3	75.0	1	25.0								
	Reboxetine	10	100	5	50.0	2	20.0	1	10.0	2	20.0						
BODY AS A WHOLE- GENERAL DISORDERS	Imipramine	10	100	3	30.0	1	10.0	2	20.0	2	20.0	2	20.0				
	Placebo	6	100			3	50.0	2	33.3	1	16.7						
	Reboxetine	7	100	4	57.1	1	14.3	1	14.3			1	14.3				

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 50

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET
BY ASSIGNED TREATMENT AND GROUPED BY BODY SYSTEM

Body system	Assigned treatment	Total	Days of treatment																				
			0-7		8-14		15-21		22-28		29-35		36-42		> 42								
			No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%							
URINARY SYSTEM DISORDERS	Imipramine	2	100	2	100																		
	Placebo	4	100	3	75.0												1	25.0					
	Reboxetine	13	100	6	46.2			4	30.8	2	15.4							1	7.7				
RESPIRATORY SYSTEM DISORDERS	Imipramine	4	100	3	75.0			1	25.0														
	Placebo	7	100	1	14.3	3	42.9	2	28.6										1	14.3			
	Reboxetine	8	100	1	12.5	1	12.5	1	12.5	2	25.0	2	25.0						1	12.5			
METABOLIC AND NUTRITIONAL DISORDERS	Imipramine	5	100	1	20.0							2	40.0							1	20.0		
	Placebo	1	100					1	100														
	Reboxetine	3	100	2	66.7							1	33.3										
REPRODUCTIVE DISORDERS, MALE	Reboxetine	3	100	3	100																		
MUSCULO-SKELETAL SYSTEM DISORDERS	Imipramine	1	100	1	100																		
	Placebo	5	100	3	60.0			1	20.0	1	20.0	1	20.0										
	Reboxetine	1	100											1	100								
SKIN AND APPENDAGES DISORDERS	Imipramine	3	100					1	33.3	1	33.3												
	Placebo	2	100																		2	100	
	Reboxetine	1	100																			1	100
SPECIAL SENSES OTHER, DISORDERS	Imipramine	1	100	1	100																		
	Placebo	1	100																				
HEARING AND VESTIBULAR DISORDERS	Imipramine	2	100	1	50.0	1	50.0																

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9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 50

ADVERSE EVENTS: OCCURRENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET
BY ASSIGNED TREATMENT AND GROUPED BY BODY SYSTEM

Body system	Assigned treatment	Days of treatment																
		Total		0-7		8-14		15-21		22-28		29-35		36-42		> 42		
		No AE	Z	No AE	Z	No AE	Z	No AE	Z	No AE	Z	No AE	Z	No AE	Z	No AE	Z	
LIVER AND BILIAR SYSTEM DISORDERS	Imipramine	1	100															
	Reboxetine	1	100				1	100										
HEMATOLOGY DISORDERS	Imipramine	2	100															
RESISTANCE MECHANISM DISORDERS	Placebo	1	100														1	100

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
All adverse events	Mild	62	55	7		60	2	
	Moderate	105	102	3		102	3	
	Severe	33	31	2		33		
	Unknown	11	9	2		10	1	
	Total	211	197	14		205	6	
MOUTH DRY	Mild	14	13	1		13	1	
	Moderate	12	12			12		
	Severe	3	3			3		
	Total	29	28	1		28	1	
SWEATING INCREASED	Mild	6	6			6		
	Moderate	8	8			8		
	Unknown	1	1			1		
	Total	15	15			15		
TREMOR	Mild	4	4			4		
	Moderate	1	1			1		
	Severe	1	1			1		
	Total	6	6			6		
CONSTIPATION	Mild	4	3	1		3	1	
	Moderate	14	14			14		
	Severe	2	2			2		
	Total	20	19	1		19	1	

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 51
 ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE
 BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Adverse events / severity	Adverse events Number		Dose taken on onset date			Highest dose taken from 3 days before		
	Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose	
DIZZINESS	Mild	3	1	2		3		
	Moderate	3	3			3		
	Unknown	2	2			2		
	Total	8	6	2		8		
NAUSEA	Mild	1	1			1		
	Moderate	7	7			7		
	Severe	1	1			1		
	Total	9	9			9		
VISION ABNORMAL	Mild	4	3	1		4		
	Moderate	1	1			1		
	Unknown	2	2			2		
	Total	7	6	1		7		
HEADACHE	Mild	4	4			4		
	Moderate	13	13			13		
	Severe	1	1			1		
	Total	18	18			18		
VERTIGO	Mild	2	2			2		
	Moderate	1	1			1		
	Severe	2	2			2		
	Total	5	5			5		
INSOMNIA	Moderate	6	6			6		

(*) all remainder patients
 REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
 IMPRIMINE - low dose <= 150 mg/day, high dose > 150 mg/day

(CONTINUED)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Adverse events / severity	Adverse events Number		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
INSOMNIA	Severe	4	4			4		
	Unknown	2	1	1		2		
	Total	12	11	1		12		
PARAESTHESIA	Moderate	2	2			2		
	Total	2	2			2		
SOMNOLENCE	Moderate	1	1			1		
	Total	1	1			1		
HYPOTENSION POSTURAL	Moderate	1	1			1		
	Severe	1		1		1		
	Total	2	1	1		2		
ABDOMINAL PAIN	Moderate	1	1			1		
	Total	1	1			1		
TACHYCARDIA	Moderate	2	2			2		
	Severe	1	1			1		
	Total	3	3			3		
HOT FLUSHES	Moderate	2	2			2		
	Total	2	2			2		
AGITATION	Mild	2	1	1		2		
	Moderate	2	1	1		1	1	
	Severe	4	4			4		
Total	8	6	2		7	1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

33
11

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 5f

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE
BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Adverse events / severity	Adverse events Number		Dose taken on onset date			Highest dose taken from 3 days before		
	Severe	Total	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
SUICIDE ATTEMPT	1	1	1			1		
FATIGUE	1	1	1			1		
ASTHENIA	1	1	1			1		
PALPITATION	3	3	3			3		
DYSPNOEA	1	1	1		1	1		
CONFUSION	4	4	4			4		
MUSCLE CONTRACTIONS INVOLUNTARY	5	5	4	1		5		
WEIGHT INCREASE	1	1	1			1		
RHINITIS	1	1	1			1		
	1	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 51
ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE
BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
HYPOTENSION	Moderate	2	2			2		
	Total	2	2			2		
VOMITING	Severe	1	1			1		
	Total	1	1			1		
DYSURIA	Mild	1	1			1		
	Moderate	1	1			1		
CHEST PAIN	Total	2	2			2		
	Severe	1	1			1		
HYPERTENSION	Total	1	1			1		
	Moderate	1	1			1		
ANXIETY	Total	1	1			1		
	Severe	1	1			1		
GAMMA-GT INCREASED	Total	1	1			1		
	Moderate	1	1			1		
MICTURITION DISORDER	Total	3	3			3		
	Mild	3	3			3		
INFLUENZA-LIKE SYMPTOMS	Total	1		1			1	
	Unknown	1		1			1	
NERVOUSNESS	Total	1	1			1		
	Mild	1	1			1		
	Total	3	3			3		
	Moderate	3	3			3		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No. : 51
 ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE
 BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
NERVOUSNESS	Total	4	4			4		
	Mild	2	2			2		
	Moderate	2	2			2		
	Total	4	4			4		
URINARY TRACT INFECTION	Total	2						
	Mild	2						
	Moderate	2						
	Total	4						
URINARY RETENTION	Total	2	2			2		
	Mild	1	1			1		
	Severe	1						
	Total	3	3			3		
HYDRIASIS	Total	2	2			2		
	Mild	2	2			2		
	Moderate	2	2			2		
	Total	2	2			2		
SINUSITIS	Total	1	1			1		
	Mild	1	1			1		
	Moderate	1						
	Total	2	2			2		
ARTHRALGIA	Total	2	2			2		
	Mild	2	2			2		
	Moderate	2						
	Total	2	2			2		
EYE ABNORMALITY	Total	1	1			1		
	Mild	1	1			1		
	Moderate	1						
	Total	1	1			1		
PYURIA	Total	1	1			1		
	Mild	1	1			1		
	Moderate	1						
	Total	1	1			1		
PERINEAL PAIN MALE	Total	1	1			1		
	Mild	1	1			1		
	Moderate	1						
	Total	1	1			1		
HYPERPREXIA	Total	1	1			1		
	Mild	1	1			1		
	Moderate	1						
	Total	1	1			1		

(CONTINUED)

(*) all remainder patients
 REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
 IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE
 BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (x)	High dose	Overdose
ANOREXIA	Moderate	1	1			1		
	Total	1	1			1		
SALIVA INCREASED	Moderate	1	1			1		
	Total	1	1			1		
GASTRITIS	Moderate	1		1			1	
	Total	1		1			1	
GASTROENTERITIS	Moderate	1		1			1	
	Total	1		1			1	
WEIGHT DECREASE	Moderate	1	1			1		
	Total	1	1			1		
HAEMORRHOIDS THROBSED	Moderate	1	1			1		
	Total	1	1			1		
EPIDIDYMITIS	Moderate	1	1			1		
	Total	1	1			1		
RASH ERYTHEMATOUS	Moderate	1	1			1		
	Total	1	1			1		
MIGRAINE	Moderate	1	1			1		
	Total	1	1			1		
FLUSHING	Moderate	1	1			1		
	Total	1	1			1		
FLATULENCE	Moderate	1	1			1		
	Total	1	1			1		

(CONTINUED)

(*) all remainder patients
 REMOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
 IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
FLATULENCE	1		1			1		
HYPERURICAEMIA	1			1		1		
	1			1		1		
IMPOTENCE	1		1			1		
	1		1			1		
LIBIDO DECREASED	1		1			1		
	1		1			1		
TOOTH DISORDER	1		1			1		
	1		1			1		

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events			Dose taken on onset date			Highest dose taken from 3 days before			
	Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
All adverse events	Mild	75	74	1				75		
	Moderate	158	151	5	2			149	7	2
	Severe	44	43	1				43	1	
	Unknown	11	10	1				11		
	Total	288	278	8	2			278	8	2
MOUTH DRY	Mild	19	18	1				19		
	Moderate	29	28	1				28	1	
	Severe	4	4					4		
	Unknown	1	1					1		
	Total	53	51	2				52	1	
SWEATING INCREASED	Mild	4	4					4		
	Moderate	15	15					15		
	Severe	6	6					6		
	Unknown	1	1					1		
	Total	26	26					26		
TREMOR	Mild	5	5					5		
	Moderate	12	11	1				11	1	
	Severe	3	3					3		
	Total	20	19	1				19	1	
CONSTIPATION	Mild	5	5					5		
	Moderate	10	10					10		

(CONTINUED)

(*) all remainder patients
REBOXETINE - Low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - Low dose <= 150 mg/day, high dose > 150 mg/day

9550082

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PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20124/015
TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events			Dose taken on onset date			Highest dose taken from 3 days before			
	Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
CONSTIPATION	Severe	2	2					2		
	Unknown	1	1					1		
	Total	18	18					18		
DIZZINESS	Mild	4	4					4		
	Moderate	10	8				2	8		2
	Severe	2	2					2		
Total	16	14				2	14			2
NAUSEA	Mild	4	4					4		
	Moderate	8	8					8		
	Severe	3	2		1			2		1
Unknown	1	1					1			
Total	16	15		1			15			1
VISION ABNORMAL	Mild	3	3					3		
	Moderate	7	6		1			6		1
	Total	10	9		1			9		1
HEADACHE	Mild	3	3					3		
	Moderate	4	3		1			4		
	Severe	2	2					2		
Total	9	8		1			9			
VERTIGO	Mild	1	1					1		
	Moderate	6	6					6		

(CONTINUED)

(*) all remainder patients
REBOMETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE
BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
VERTIGO	Severe	1	1			1		
	Total	8	8			8		
	Moderate	1	1			1		
INSOMNIA	Severe	5	5			5		
	Unknown	2	1	1		2		
	Total	8	7	1		8		
PARAESTHESIA	Mild	1	1			1		
	Moderate	3	3			3		
	Severe	1	1			1		
	Unknown	1	1			1		
	Total	6	6			6		
	Mild	2	2			2		
SOMNOLENCE	Moderate	4	4			4		
	Total	6	6			6		
	Moderate	3	3			3		
HYPOTENSION POSTURAL	Severe	3	3			3		
	Total	6	6			6		
	Mild	2	2			2		
ABDOMINAL PAIN	Moderate	3	3			3		
	Total	5	5			5		
	Mild	2	2			2		
DYSPEPSIA	Mild	2	2			2		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
DYSPEPSIA	Moderate	1	1				1	
	Severe	2	2				2	
	Total	5	5				5	
TACHYCARDIA	Mild	2	2				2	
	Severe	1	1				1	
	Unknown	1	1				1	
Total	4	4				4		
HOT FLUSHES	Mild	1	1				1	
	Moderate	2	2				2	
	Severe	1	1				1	
Total	4	4				4		
AGITATION	Moderate	4	4				4	
	Total	4	4				4	
	Moderate	2	2				2	
SUICIDE ATTEMPT	Severe	1	1				1	
	Unknown	1	1				1	
	Total	4	4				4	
FATIGUE	Moderate	3	3				3	
	Severe	1	1				1	
	Total	4	4				4	
ASTHENIA	Moderate	2	2				2	

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20124/015

TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
ASTHENIA	Severe	1	1			1		
	Total	3	3			3		
PALPITATION	Mild	2	2			2		
	Total	2	2			2		
CONJUNCTIVITIS	Mild	2	2			2		
	Total	2	2			2		
TINNITUS	Mild	1	1			1		
	Moderate	1	1			1		
DISPNOEA	Total	2	2			2		
	Mild	1	1			1		
CHEST PAIN PRECORDIAL	Moderate	1	1			1		
	Total	2	2			2		
CONFUSION	Mild	1	1			1		
	Severe	1	1			1		
MUSCLE CONTRACTIONS INVOLUNTARY	Total	2	2			2		
	Moderate	1	1			1		
APPETITE INCREASED	Unknown	1	1			1		
	Total	2	2			2		
APPETITE INCREASED	Moderate	2	2			2		
	Total	2	2			2		

(CONTINUED)

(*) all remainder patients
 REBOMETINE - low dose <= 8 mg/day, high dose > 8 mg/day
 INIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
APETITE INCREASED	2		2			2		
WEIGHT INCREASE	2		2			2		
RHINITIS	2		2			2		
SYNCOPE	2		2			2		
SPEECH DISORDER	1		1			1		
HYPOTENSION	1		1			1		
VOMITING	1		1			1		
AUTOLESIONIST BEHAVIOUR	1		1			1		
SLEEP DISORDER	1		1			1		
HYPOKALAEMIA	1		1			1		
HYPERTRICHERIDIA	1		1			1		
	1		1			1		

(CONTINUED)

(*) all remainder patients
 REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
 IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
ANAEMIA HYPOCHROMIC	Mild	1	1				1	
	Total	1	1				1	
DYSURIA	Mild	1	1				1	
	Total	1	1				1	
CHEST PAIN	Mild	1	1				1	
	Total	1	1				1	
RHAGADES	Moderate	1	1				1	
	Total	1	1				1	
COLD URTICARIA	Moderate	1	1				1	
	Total	1	1				1	
MYALGIA	Moderate	1	1				1	
	Total	1	1				1	
HYPERKINESIA	Moderate	1	1				1	
	Total	1	1				1	
ACCOMMODATION ABNORMAL	Moderate	1	1				1	
	Total	1	1				1	
HYPERTENSION	Moderate	1	1				1	
	Total	1	1				1	
TASTE LOSS	Moderate	1	1				1	
	Total	1	1				1	
ANXIETY	Moderate	1	1				1	
	Total	1	1				1	

(CONTINUED)

(*) all remainder patients
 REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
 IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
ANXIETY	1		1			1		
CONCENTRATION IMPAIRED	1			1			1	
COLITIS	1			1			1	
DUODENAL ULCER REACTIVATED	1		1			1		
DYSFRACIA	1		1			1		
GAMMA-GT INCREASED	1		1			1		
PHOSPHATASE ALKALINE INCREASED	1		1			1		
EXTRASYSTOLES	1		1			1		
EOSINOPHILIA	1		1			1		
MICTURITION DISORDER	1		1			1		
RIGORS	1		1			1		
Total	1		1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 51

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Imipramine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
RASH	Severe	1	1			1		
	Total	1	1			1		
DEPERSONALIZATION	Severe	1	1			1		
	Total	1	1			1		
INFLUENZA-LIKE SYMPTOMS	Unknown	1	1			1		
	Total	1	1			1		

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

9550082

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 52

ADVERSE EVENTS: NUMBER OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT BY MAXIMAL SEVERITY LEVEL, SEX, AGE, DSMIII

Assigned treatment / Severity level	Sex						Age						DSM III						
	Total		Female		Male		18 - 30		31 - 45		> 45		296.2		296.3		296.5		
	No. Pt	Z	No. Pt	Z	No. Pt	Z	No. Pt	Z	No. Pt	Z	No. Pt	Z	No. Pt	Z	No. Pt	Z	No. Pt	Z	
Imipramine	1	1.2			1	3.7					1	2.6			1	1.8			
	14	17.3	5	9.3	9	33.3	1	8.3	5	16.1	8	21.1	6	25.0	8	14.3			
	41	50.6	28	51.9	13	48.1	9	75.0	11	35.5	21	55.3	9	37.5	31	55.4	1	100.0	
	25	30.9	21	38.9	4	14.8	2	16.7	15	48.4	8	21.1	9	37.5	16	28.6			
	81	108.0	54	100.0	27	100.0	12	100.0	31	100.0	38	100.0	24	100.0	56	100.0	1	100.0	
Placebo	1	1.7			1	3.4					1	4.5			1	2.2			
	16	27.6	8	27.6	8	27.6	1	12.5	9	32.1	6	27.3	8	66.7	8	17.4			
	30	51.7	15	51.7	15	51.7	5	62.5	13	46.4	12	54.5	4	33.3	26	56.5			
	11	19.0	6	20.7	5	17.2	2	25.0	6	21.4	3	13.6			11	23.9			
	58	100.0	29	100.0	29	100.0	8	100.0	28	100.0	22	100.0	12	100.0	46	100.0			
Reboxetine	20	28.2	9	20.5	11	40.7	3	30.0	6	20.7	11	34.4	7	35.0	13	25.5			
	28	39.4	21	47.7	7	25.9	4	40.0	13	44.8	11	34.4	6	30.0	22	43.1			
	23	32.4	14	31.8	9	33.3	3	30.0	10	34.5	10	31.3	7	35.0	16	31.4			
	71	100.0	44	100.0	27	100.0	10	100.0	29	100.0	32	100.0	20	100.0	51	100.0			

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																														
	Imipramine									Placebo									Reboxetine												
	Female			Male			Total			Female			Male			Total			Female			Male			Total						
	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z							
All adverse events	Mild	5	9.3	9.3	9	34.6	33.3	14	17.5	17.3	8	27.6	27.6	8	28.6	27.6	16	28.1	27.6	9	20.5	20.5	11	40.7	40.7	20	28.2	28.2			
	Moderate	28	51.9	51.9	43	50.0	48.1	41	51.3	50.6	15	51.7	51.7	15	53.6	51.7	30	52.6	51.7	21	47.7	47.7	7	25.9	25.9	28	39.4	39.4			
	Severe	21	38.9	38.9	4	15.4	14.8	25	31.3	30.9	6	20.7	20.7	5	17.9	17.2	11	19.3	19.0	14	31.8	31.8	9	33.3	33.3	23	32.4	32.4			
	Total	54	100	100	26	100	96.3	80	100	98.8	29	100	100	28	100	96.6	57	100	98.3	44	100	100	27	100	100	71	100	100			
MOUTH DRY	Mild	8	22.9	14.8	9	64.3	33.3	17	34.7	21.0	5	50.0	17.2	2	50.0	6.9	7	50.0	12.1	7	36.8	15.9	7	77.8	25.9	14	50.0	19.7			
	Moderate	29	65.7	42.6	4	28.6	14.8	27	55.1	33.3	4	40.0	13.8	2	50.0	6.9	6	42.9	10.3	9	47.4	20.5	2	22.2	7.4	11	39.3	15.5			
	Severe	3	8.6	5.6	1	7.1	3.7	4	8.2	4.9	1	10.0	3.4				1	7.1	1.7	3	15.8	6.8				3	10.7	4.2			
	Missing	1	2.9	1.9				1	2.0	1.2																					
CONSTIPATION	Total	35	100	64.8	14	100	51.9	49	100	60.5	10	100	34.5	4	100	13.8	14	100	24.1	19	100	43.2	9	100	33.3	28	100	39.4			
	Mild	2	14.3	3.7	3	75.0	11.1	5	27.8	6.2	1	20.0	3.4	1	100	3.4	2	33.3	3.4							3	60.0	11.1	3	17.6	4.2
	Moderate	9	64.3	16.7	1	25.0	3.7	10	55.6	12.3	4	80.0	13.8				4	66.7	6.9	11	91.7	25.0	1	20.0	3.7	12	70.6	16.9			
	Severe	2	14.3	3.7				2	11.1	2.5											1	8.3	2.3	1	20.0	3.7	2	11.8	2.8		
SWEATING INCREASED	Missing	1	7.1	1.9				1	5.6	1.2																					
	Total	14	100	25.9	4	100	14.8	18	100	22.2	5	100	17.2	1	100	3.4	6	100	10.3	12	100	27.3	5	100	18.5	17	100	23.9			
	Mild	2	12.5	3.7	1	16.7	3.7	3	13.6	3.7																					
	Moderate	10	62.5	18.5	3	50.0	11.1	13	59.1	16.0	2	100	6.9	1	100	3.4	3	100	5.2	6	54.5	13.6	2	66.7	7.4	8	57.1	11.3			
HEADACHE	Severe	3	18.8	5.6	2	33.3	7.4	5	22.7	6.2																					
	Missing	1	6.3	1.9				1	4.5	1.2																					
	Total	16	100	29.6	6	100	22.2	22	100	27.2	2	100	6.9	1	100	3.4	3	100	5.2	11	100	25.0	3	100	11.1	14	100	19.7			
	Mild	2	28.6	3.7	1	50.0	3.7	3	33.3	3.7	1	33.3	3.4	2	33.3	6.9	5	33.3	5.2	4	40.0	9.1					4	28.6	5.6		

(CONTINUED)

(*) Z on all patients with adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 53

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																														
	Imipramine									Placebo									Reboxetine												
	Female			Male			Total			Female			Male			Total			Female			Male			Total						
	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z				
HEADACHE	Moderate	3	42.9	5.5	1	50.0	3.7	4	44.4	4.9	2	66.7	6.9	4	66.7	13.8	6	66.7	10.3	6	60.0	13.6	3	75.0	11.1	9	64.3	12.7			
	Severe	2	28.6	3.7				2	22.2	2.5														1	25.0	3.7	1	7.1	1.4		
	Total	7	100	13.0	2	100	7.4	9	100	11.1	3	100	10.3	6	100	20.7	9	100	15.5	10	100	22.7	4	100	14.8	14	100	19.7			
TREMOR	Mild	4	25.0	7.4	1	25.0	3.7	5	25.0	6.2				1	33.3	3.4	1	20.0	1.7	3	75.0	6.8	1	50.0	3.7	4	66.7	5.6			
	Moderate	9	56.3	16.7	3	75.0	11.1	12	60.0	14.8	2	100	6.9	1	33.3	3.4	3	60.0	5.2					1	50.0	3.7	1	16.7	1.4		
	Severe	3	18.8	5.6				3	15.0	3.7				1	33.3	3.4	1	20.0	1.7	1	25.0	2.3					1	16.7	1.4		
NAUSEA	Total	16	100	29.6	4	100	14.8	20	100	24.7	2	100	6.9	3	100	10.3	5	100	8.6	4	100	9.1	2	100	7.4	6	100	8.5			
	Mild	2	18.2	3.7	1	50.0	3.7	3	23.1	3.7	3	37.5	10.3	1	100	3.4	4	44.4	6.9	1	16.7	2.3				1	11.1	1.4			
	Moderate	6	54.5	11.1				6	46.2	7.4	5	62.5	17.2				5	55.6	8.6				2	66.7	7.4	7	77.8	9.9			
DIZZINESS	Severe	2	18.2	3.7	1	50.0	3.7	3	23.1	3.7																1	11.1	1.4			
	Missing	1	9.1	1.9				1	7.7	1.2																					
	Total	11	100	20.4	2	100	7.4	13	100	16.0	8	100	27.6	1	100	3.4	9	100	15.5	6	100	13.6	3	100	11.1	9	100	12.7			
INSOMNIA	Mild	3	30.0	5.6	1	25.0	3.7	4	28.6	4.9				2	50.0	6.9	2	50.0	3.4					3	100	11.1	3	50.0	4.2		
	Moderate	5	50.0	9.3	3	75.0	11.1	8	57.1	9.9				2	50.0	6.9	2	50.0	3.4				3	100	6.8			3	50.0	4.2	
	Severe	2	20.0	3.7				2	14.3	2.5																					
TOTAL	Total	10	100	18.5	4	100	14.8	14	100	17.3				4	100	13.8	4	100	6.9	3	100	6.8	3	100	6.8	3	100	11.1	6	100	8.5
	Moderate				1	50.0	3.7	1	12.5	1.2	1	50.0	3.4	1	50.0	3.4	2	50.0	3.4	3	42.9	6.8	3	60.0	11.1	6	50.0	8.5			
	Severe	5	83.3	9.3				5	62.5	6.2				1	50.0	3.4	1	25.0	1.7	3	42.9	6.8	1	20.0	3.7	4	33.3	5.6			
TOTAL	Missing	1	16.7	1.9	1	50.0	3.7	2	25.0	2.5	1	50.0	3.4				1	25.0	1.7	1	14.3	2.3	1	20.0	3.7	2	16.7	2.8			
	Total	6	100	11.1	2	100	7.4	8	100	9.9	2	100	6.9	2	100	6.9	4	100	6.9	7	100	15.9	5	100	16.5	12	100	16.9			

(CONTINUED)

(*) Z on all patients with adverse events

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																											
	Imipranine						Placebo						Reboxetine															
	Female		Male		Total		Female		Male		Total		Female		Male		Total											
No. Pt.	(*) %	No. Pt.	(*) %	No. Pt.	(*) %	No. Pt.	(*) %	No. Pt.	(*) %	No. Pt.	(*) %	No. Pt.	(*) %	No. Pt.	(*) %	No. Pt.	(*) %	No. Pt.	(*) %									
AGITATION	Mild	2	100	3.7	2	100	7.4	4	100	4.9	2	33.3	6.9	2	28.6	3.4	2	66.7	7.4	2	28.6	2.8						
	Moderate																											
	Severe																											
Total	2	100	3.7	2	100	7.4	4	100	4.9	2	33.3	6.9	2	28.6	3.4	2	66.7	7.4	2	28.6	2.8							
VISION ABNORMAL	Mild	2	33.3	3.7	1	33.3	3.7	3	33.3	3.7	3	33.3	3.4	1	33.3	1.7	2	66.7	4.5	1	33.3	3.7	3	50.0	4.2			
	Moderate	4	66.7	7.4	2	66.7	7.4	6	66.7	7.4	6	66.7	6.9	2	66.7	3.4	2	66.7	6.9	2	66.7	3.7	1	16.7	1.4			
	Missing																											
Total	6	100	11.1	3	100	11.1	9	100	11.1	9	100	10.3	3	100	5.2	3	100	6.8	3	100	11.1	6	100	8.5				
SOMNOLENCE	Mild	1	25.0	1.9	1	50.0	3.7	2	33.3	2.5	1	25.0	3.4	3	60.0	10.3	4	44.4	6.9									
	Moderate	3	75.0	5.6	1	50.0	3.7	4	66.7	4.9	3	75.0	10.3	2	40.0	6.9	5	55.6	8.6	1	100	2.3	1	100	1.4			
	Total	4	100	7.4	2	100	7.4	6	100	7.4	4	100	13.8	5	100	17.2	9	100	15.5	1	100	2.3	1	100	1.4			
VERTIGO	Mild	1	14.3	1.9				1	14.3	1.2							2	50.0	4.5				2	40.0	2.8			
	Moderate	5	71.4	9.3				5	71.4	6.2							1	25.0	2.3				1	20.0	1.4			
	Severe	1	14.3	1.9				1	14.3	1.2							4	100	9.1	1	100	3.7	2	40.0	2.8			
Total	7	100	13.0				7	100	8.6							4	100	9.1	1	100	3.7	5	100	7.0				
FATIGUE	Mild																						1	50.0	3.7	1	33.3	1.4
	Moderate	2	66.7	3.7	1	100	3.7	3	75.0	3.7	1	100	3.4	3	100	10.3	4	100	6.9									
	Severe	1	33.3	1.9				1	25.0	1.2							1	100	2.3				1	50.0	3.7	1	33.3	1.4
Total	3	100	5.6	1	100	3.7	4	100	4.9	1	100	3.4	3	100	10.3	4	100	6.9	1	100	2.3	2	100	7.4	3	100	4.2	

(CONTINUED)

(*) % on all patients with adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 53

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																		
	Imipramine						Placebo						Reboxetine						
	Female		Male		Total		Female		Male		Total		Female		Male		Total		
No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z		
PARAESTHESIA	Mild	1 20.0	1.9			1 16.7	1.2	1 100	3.4			1 50.0	1.7						
	Moderate	3 60.0	5.6			3 50.0	3.7					1 100	2.3	1 100	3.7	2 100	2.8		
	Severe			1 100	3.7	1 16.7	1.2												
	Missing	1 20.0	1.9			1 16.7	1.2												
Total	5 100	9.3	1 100	3.7	6 100	7.4	1 100	3.4	1 100	3.4	2 100	3.4	1 100	2.3	1 100	3.7	2 100	2.8	
SUICIDE ATTEMPT	Mild					1 33.3	3.4					1 25.0	1.7						
	Moderate	1 50.0	1.9	1 50.0	3.7	2 50.0	2.5	1 33.3	3.4			1 25.0	1.7						
	Severe	1 50.0	1.9			1 25.0	1.2	1 33.3	3.4	1 100	3.4	2 50.0	3.4	1 100	2.3			1 100	1.4
	Missing			1 50.0	3.7	1 25.0	1.2												
Total	2 100	3.7	2 100	7.4	4 100	4.9	3 100	10.3	1 100	3.4	4 100	6.9	1 100	2.3			1 100	1.4	
HYPOTENSION POSTURAL	Moderate	3 60.0	5.6			3 50.0	3.7							1 50.0	2.3			1 50.0	1.4
	Severe	2 40.0	3.7	1 100	3.7	3 50.0	3.7							1 50.0	2.3			1 50.0	1.4
	Total	5 100	9.3	1 100	3.7	6 100	7.4							2 100	4.5			2 100	2.8
	Mild	1 33.3	1.9			1 25.0	1.2												
Total	2 66.7	3.7	1 100	3.7	3 75.0	3.7	2 100	6.9	1 100	3.4	3 100	5.2	1 100	2.3			1 100	1.4	
TACHYCARDIA	Mild	3 100	5.6	1 100	3.7	4 100	4.9	2 100	6.9	1 100	3.4	3 100	5.2	1 100	2.3			1 100	1.4
	Moderate	2 50.0	3.7			2 50.0	2.5												
	Severe	1 25.0	1.9			1 25.0	1.2												
	Missing	1 25.0	1.9			1 25.0	1.2												
Total	6 100	10.3	4 100	7.4	10 100	12.6	6 100	13.8	2 100	6.8	6 100	11.4	2 100	4.6			2 100	4.6	

(CONTINUED)

(*) Z on all patients with adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																	
	Imipramine						Placebo						Reboxetine					
	Female		Male		Total		Female		Male		Total		Female		Male		Total	
No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	No. Pt.	(*) Z	
ANXIETY	Mild																	
	Moderate			1	100 3.7	1	100 1.2											
	Severe																	
NERVOUSNESS	Total			1	100 3.7	1	100 1.2											
	Mild																	
	Moderate																	
DYSPNOEA	Total																	
	Mild	1	50.0 1.9															
	Moderate	1	50.0 1.9															
MICTURITION DISORDER	Total	2	100 3.7			2	100 2.5											
	Mild																	
	Moderate	1	100 1.9			1	100 1.2											
URINARY TRACT INFECTION	Total	1	100 1.9			1	100 1.2											
	Mild																	
	Moderate																	
URINARY RETENTION	Total																	
	Mild																	
	Severe																	
PALPITATION	Total																	
	Mild	1	100 1.9	1	100 3.7	2	100 2.5											

(*) Z on all patients with adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 53

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																						
	Imipramine									Placebo													
	Female			Male			Total	Female			Male			Total	Female			Male			Total		
	No. Pt.	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	
PALPITATI-ON	Moderate																						
	Total	1	100	1.9	1	100	3.7	2	100	2.5													
ASTHENIA	Moderate	1	100	1.9	1	150.0	3.7	2	66.7	2.5													
	Severe				1	50.0	3.7	1	33.3	1.2													
	Total	1	100	1.9	2	100	7.4	3	100	3.7													
RASH	Mild																						
	Moderate																						
	Severe	1	100	1.9				1	100	1.2													
HYPERKINESIA	Mild	1	100	1.9																			
	Moderate																						
	Total	1	100	1.9																			
CONFUSION	Mild																						
	Moderate	1	50.0	1.9																			
	Severe																						
HYPERKINESIA	Missing	1	50.0	1.9																			
	Total	2	100	3.7																			
	Moderate	1	100	1.9																			
CONFUSION	Severe																						
	Total	1	100	1.9																			
	Moderate	1	100	1.9																			
CONFUSION	Severe																						
	Total	1	100	1.9																			
	Moderate	1	100	1.9																			

(CONTINUED)

(*) Z on all patients with adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 53

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																										
	Inipramine									Placebo									Reboxetine								
	Female			Male			Total			Female			Male			Total			Female			Male			Total		
	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z			
MUSCLE CONTRACTI-ONS				2	100	7.4																					
INVOLENTA-RY				2	100	7.4																					
DIARRHOEA									1	100	3.4				2	100	6.9										
Total									1	100	3.4			2	100	6.9											
APETITE INCREASED				2	100	3.7																					
Total				2	100	3.7																					
WEIGHT INCREASE				2	100	3.7																					
Total				2	100	3.7																					
SINUSITIS																											
Severe																											
Total																											
DYSURIA				1	100	3.7																					
Mild																											
Moderate																											
Total				1	100	3.7																					
CHEST PAIN PRECORDIAL				1	50.0	1.9																					
Severe																											
Total				1	50.0	1.9																					
INFLUENZA-LIKE SYMPTOMS				1	100	1.9																					
Total				1	100	1.9																					

(CONTINUED)

(*) Z on all patients with adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																										
	Imipramine									Placebo									Reboxetine								
	Female			Male			Total			Female			Male			Total			Female			Male			Total		
	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z			
ACCUMULATION	1	100	1.9																								
ABNORMAL	1	100	1.9																								
FLUSHING																											
BRADYCARDIA																											
SALIVA INCREASED																											
CHROMATOPSIA																											
EYE ABNORMALITY																											
TASTE LOSS	1	100	1.9																								
TASTE PERVERSION																											
AUTOLESIONIST BEHAVIOUR	1	100	1.9																								
DEPERSONALIZATION	1	100	1.9																								
Total	1	100	1.9																								

(CONTINUED)

(*) % on all patients with adverse events

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PHARMACIA CNS REP
REBOMETIN - PROTOCOL 20124/015
TABLE No. 1.53

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																						
	Iraperidone						Placebo																
	Female			Male			Female			Male													
	No. Pt.	(*) Z	(*) X	No. Pt.	(*) Z	(*) X	No. Pt.	(*) Z	(*) X	No. Pt.	(*) Z	(*) X											
DYSIDROPIA	Moderate	1	100	1.9																			
	Total	1	100	1.9																			
MIGRAINE	Mild						1	100	3.4	1	100	1.7											
	Total						1	100	3.4	1	100	1.7											
PRURIA	Mild																						
	Total																						
IMPOTENCE	Severe																						
	Total																						
PERINEAL PAIN MALE	Mild																						
	Total																						
STIMULUS TIS	Moderate																						
	Total																						
MALAISE	Moderate																						
	Total																						
RIGORS	Moderate																						
	Total																						
HYPEREMESIS XIA	Mild																						
	Total																						
PNEUMONITIS	Mild																						
	Total																						

(CONTINUED)

(*) X on all patients with adverse events

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PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																					
	Imipramine						Placebo						Total		Reboxetine							
	Female			Male			Female			Male			Total		Female			Male			Total	
	No. Pt.	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	No. Pt.	(*) Z	(*) Z	
Mild						1	100	3.4							1	100	1.7					
Total						1	100	3.4							1	100	1.7					

341

(*) Z on all patients with adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 54

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS, GROUPED BY BODY SYSTEM, BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Body system / Severity	Assigned treatment																											
	Imipramine									Placebo									Reboxetine									
	Female			Male			Total			Female			Male			Total			Female			Male			Total			
	No.	(*)	Z	No.	(*)	Z	No.	(*)	Z	No.	(*)	Z	No.	(*)	Z	No.	(*)	Z	No.	(*)	Z	No.	(*)	Z	No.	(*)	Z	
All adverse events	Mild	5	9.3	9.3	9	34.6	33.3	14	17.5	17.3	8	27.6	27.6	8	28.5	27.6	16	28.1	27.6	9	20.5	20.5	11	40.7	40.7	20	28.2	28.2
	Moderate	28	51.9	51.9	13	50.0	48.1	41	51.3	50.6	15	51.7	51.7	15	55.6	51.7	30	52.6	51.7	21	47.7	47.7	7	25.9	25.9	28	39.4	39.4
	Severe	21	38.9	38.9	4	15.4	14.8	25	31.3	30.9	6	20.7	20.7	5	17.9	17.2	11	19.3	19.0	14	31.8	31.8	9	33.3	33.3	23	32.4	32.4
	Total	54	100	100	26	100	96.3	80	100	98.8	29	100	100	28	100	96.6	57	100	98.3	44	100	100	27	100	100	71	100	100
AUTONOMIC NERVOUS SYSTEM DISORDERS	Mild	7	17.9	13.0	8	47.1	29.6	15	25.8	18.5	5	41.7	17.2	2	40.0	6.9	7	41.2	12.1	10	37.0	22.7	8	61.5	29.6	18	45.0	25.4
	Moderate	25	64.1	46.3	7	41.2	25.9	32	57.1	39.5	6	50.0	20.7	3	60.0	10.3	9	52.9	15.5	14	51.9	31.8	5	38.5	18.5	19	47.5	26.8
	Severe	6	15.4	11.1	2	11.8	7.4	8	14.3	9.9	1	8.3	3.4				1	5.9	1.7	3	11.1	6.8				3	7.5	4.2
	Missing	1	2.6	1.9				1	1.8	1.2																		
Total	39	100	72.2	17	100	63.0	56	100	69.1	12	100	41.4	5	100	17.2	17	100	29.3	27	100	61.4	13	100	48.1	40	100	56.3	
GASTRO-INTESTINAL SYSTEM DISORDERS	Mild	5	17.9	9.3	4	50.0	14.8	9	25.0	11.1	3	23.1	10.3	2	40.0	6.9	5	27.8	8.6	1	5.3	2.3	2	28.6	7.4	3	11.5	4.2
	Moderate	18	64.3	33.3	2	25.0	7.4	20	55.6	24.7	9	69.2	31.0	3	60.0	10.3	12	66.7	20.7	15	78.9	34.1	2	28.6	7.4	17	65.4	23.9
	Severe	5	17.9	9.3	2	25.0	7.4	7	19.4	8.6	1	7.7	3.4				1	5.6	1.7	2	10.5	4.5	3	42.9	11.1	5	19.2	7.0
	Missing																											
Total	28	100	51.9	8	100	29.6	36	100	44.4	13	100	44.8	5	100	17.2	18	100	31.0	19	100	43.2	7	100	25.9	26	100	36.6	
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Mild	6	20.0	11.1	1	16.7	3.7	7	19.4	8.6	2	28.6	6.9	2	22.2	6.9	4	25.0	6.9	8	44.4	18.2				8	29.6	11.3
	Moderate	18	60.0	33.3	4	66.7	14.8	22	61.1	27.2	4	57.1	13.8	6	66.7	20.7	10	62.5	17.2	8	44.4	18.2	5	55.6	18.5	13	48.1	18.3
	Severe	5	16.7	9.3	1	16.7	3.7	6	16.7	7.4	1	14.3	3.4	1	11.1	3.4	2	12.5	3.4	2	11.1	4.5	4	44.4	14.8	6	22.2	8.5
	Missing	1	3.3	1.9				1	2.8	1.2																		
Total	30	100	55.6	6	100	22.2	36	100	44.4	7	100	24.1	9	100	31.0	16	100	27.6	18	100	40.9	9	100	33.3	27	100	38.0	

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(*) % on all patients with adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20324/015
TABLE No.: 54
NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS, GROUPED BY BODY SYSTEM, BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Body system / Severity	Assigned treatment																																		
	Imipramine									Placebo									Reboxetine																
	Female			Male			Total			Female			Male			Total			Female			Male			Total										
	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z	No. Pt.	(*) %	Z								
URINARY SYSTEM DISORDERS	Mild			1	100	3.7			1	100	3.7			2	100	6.9			2	100	3.4			3	60.0	6.8	5	71.4	18.5	8	66.7	11.3			
	Moderate	1	100	1.9					1	100	1.2			2	100	6.9			2	100	3.4			2	40.0	4.5	1	14.3	3.7	3	25.0	4.2			
	Severe																																		
	Total	1	100	1.9	1	100	3.7	2	100	2.5	2	100	6.9	4	100	6.9	4	100	11.4	7	100	25.9	12	100	16.9										
RESPIRATORY SYSTEM DISORDERS	Mild	4	25.0	1.9					1	25.0	1.2			4	66.7	13.8			5	71.4	8.6														
	Moderate	3	75.0	5.6					3	75.0	3.7								4	100	9.1														
	Severe																																		
	Missing																																		
METABOLIC AND NUTRITIONAL DISORDERS	Total	4	100	7.4					4	100	4.9			6	100	20.7			7	100	12.1														
	Mild	2	40.0	3.7					2	40.0	2.5																								
	Moderate	3	60.0	5.6					3	60.0	3.7			1	100	3.4			1	100	1.7														
	Severe																																		
MUSCULOSKELETAL SYSTEM DISORDERS	Total	5	100	9.3					5	100	6.2			1	100	3.4			1	100	1.7														
	Mild													2	100	6.9			2	40.0	3.4														
	Moderate	1	100	3.7					1	100	1.2			3	100	10.3			3	60.0	5.2														
	Total	1	100	3.7	1	100	1.2	3	100	10.3	5	100	6.2	1	100	3.4	1	100	1.7	1	100	2.3	1	100	2.3	1	100	3.7	1	100	3.7	2	100	2.8	
SKIN AND APPENDAGES DISORDERS	Mild																																		
	Moderate	1	50.0	1.9	1	100	3.7	2	66.7	2.5	1	50.0	3.4					1	50.0	1.7															
	Severe	1	50.0	1.9					1	33.3	1.2																								
	Total	2	100	3.7	1	100	3.7	3	100	3.7	2	100	6.9						2	100	3.4														

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(*) % on all patients with adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 54

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS, GROUPED BY BODY SYSTEM, BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Body system / Severity	Assigned treatment																										
	Inipramine									Placebo									Reboxetine								
	Female			Male			Total			Female			Male			Total			Female			Male			Total		
	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z	No. Pt.	Z	(*) Z			
HEARING AND VESTIBULAR DISORDERS	Mild	1	100	1.9			1	50.0	1.2																		
	Moderate				1	100	3.7	1.2																			
	Total	1	100	1.9	1	100	3.7	2	100	2.5																	
HEMATOLOGY DISORDERS	Mild	1	50.0	1.9			1	50.0	1.2																		
	Moderate	1	50.0	1.9			1	50.0	1.2																		
	Total	2	100	3.7			2	100	2.5																		
LIVER AND BILIAR SYSTEM DISORDERS	Moderate	1	100	1.9			1	100	1.2																		
	Total	1	100	1.9			1	100	1.2																		
	Total																										
REPRODUCTIVE DISORDERS, MALE	Mild																										
	Severe																										
	Total																										
SPECIAL SENSES OTHER DISORDERS	Moderate	1	100	1.9			1	100	1.2			1	100	3.4													
	Total	1	100	1.9			1	100	1.2			1	100	3.4													
	Total																										
RESISTANCE MECHANISM DISORDERS	Mild											1	100	3.4													
	Total											1	100	3.4													
	Total											1	100	1.7													

(*) % on all patients with adverse events

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 55

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)				
		Min	50%	Max		
All adverse events	Imipramine	288	1	13	40	57
	Placebo	141	1	8	28	46
	Reboxetine	211	1	10	35	43
MOUTH DRY	Imipramine	53	1	20	41	44
	Placebo	15	2	15	44	46
	Reboxetine	23	1	26	41	42
SWEATING INCREASED	Imipramine	26	1	14	39	43
	Placebo	3	1	35	38	38
	Reboxetine	15	2	15	35	43
CONSTIPATION	Imipramine	18	7	23	40	41
	Placebo	6	3	20	40	40
	Reboxetine	20	3	13	38	41
HEADACHE	Imipramine	9	1	7	41	41
	Placebo	10	1	7	35	41
	Reboxetine	18	1	6	40	43
NAUSEA	Imipramine	16	1	6	21	42
	Placebo	11	1	6	12	13
	Reboxetine	9	2	18	24	24
TREMOR	Imipramine	20	7	20	37	41
	Placebo	5	1	3	8	8
	Reboxetine	6	4	11	14	14
DIZZINESS	Imipramine	16	1	8	19	31

(CONTINUED)

(*) adverse event present before start treatment: onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study: end date = visit date of last report visit

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 55

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)				
		Min	50%	Max		
DIZZINESS	Placebo	4	1	3	25	25
	Reboxetine	8	1	6	29	29
INSOMNIA	Imipramine	8	6	8	42	42
	Placebo	4	8	17	28	28
VISION ABNORMAL	Reboxetine	12	1	6	29	40
	Imipramine	10	3	15	39	42
	Placebo	3	33	34	36	36
	Reboxetine	7	1	12	15	15
AGITATION	Imipramine	4	1	21	36	36
	Placebo	7	2	7	28	28
	Reboxetine	8	1	9	22	22
	Imipramine	6	4	26	42	42
SOMNOLENCE	Placebo	10	7	13	21	21
	Reboxetine	1	27	27	27	27
VERTIGO	Imipramine	8	3	5	21	21
	Reboxetine	5	1	6	43	43
FATIGUE	Imipramine	4	12	15	29	29
	Placebo	4	7	15	35	35
	Reboxetine	3	1	5	35	35
	Imipramine	6	3	11	36	36
PARAESTHESIA	Placebo	2	5	5	5	5
	Reboxetine	2	2	3	4	4

(CONTINUED)

(*) adverse event present before start treatment; onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study; end date = visit date of last report visit

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)			
		Min	50%	Max	
SUICIDE ATTEMPT	Imipramine	4	1	3	67
	Placebo	4	1	4	7
ABDOMINAL PAIN	Reboxetine	1	2	2	2
	Imipramine	5	4	10	35
HYPOTENSION POSTURAL	Placebo	3	6	9	12
	Reboxetine	1	20	20	20
TACHYCARDIA	Imipramine	6	3	5	10
	Reboxetine	2	8	15	22
DYSPNOEA	Imipramine	4	1	3	15
	Reboxetine	3	3	8	16
RHINITIS	Imipramine	2	2	3	4
	Reboxetine	5	1	1	7
HOT FLUSHES	Imipramine	2	15	28	41
	Placebo	4	2	7	13
VOMITING	Reboxetine	1	15	15	15
	Imipramine	4	8	15	27
DISPEPSIA	Placebo	1	10	10	10
	Reboxetine	2	15	21	27
DISPEPSIA	Imipramine	1	2	2	2
	Placebo	4	1	4	4
DISPEPSIA	Reboxetine	1	2	2	2
	Imipramine	5	1	8	30

(CONTINUED)

(*) adverse event present before start treatment: onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study: end date = visit date of last report visit

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)		
		Min	50%	Max
DYSPEPSIA	1	12	12	12
HYPOTENSION	1	1	1	1
	2	10	12	13
ANXIETY	2	8	9	10
	1	4	4	4
	3	1	4	8
	1	3	3	3
NERVOUSNESS	1	10	10	10
	4	1	11	43
	1	43	43	43
MICTURITION DISORDER	1	7	7	7
	3	19	22	34
URINARY TRACT INFECTION	1	5	5	5
	4	8	12	14
URINARY RETENTION	1	1	1	1
	3	6	32	37
PALPITATION	2	5	24	43
	1	1	1	1
ASTHENIA	1	5	5	5
	3	3	29	31
RASH	1	3	3	3
	1	14	14	14

(CONTINUED)

(*) adverse event present before start treatment: onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study: end date = visit date of last report visit

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)			
		Min	50%	90%	Max
RASH	2	4	5	5	5
MYALGIA	1	9	9	9	9
CONFUSION	2	1	4	7	7
	2	3	9	15	15
HYPERKINESIA	1	4	4	4	4
	1	7	7	7	7
	2	7	13	19	19
MUSCLE CONTRACTIONS INVOLUNTARY	2	14	19	23	23
	1	5	5	5	5
DIARRHOEA	3	4	6	12	12
APPETITE INCREASED	2	40	41	41	41
	1	10	10	10	10
WEIGHT INCREASE	2	20	30	40	40
	1	41	41	41	41
SINUSITIS	1	27	27	27	27
	2	5	7	8	8
DYSURIA	1	3	3	3	3
	2	1	5	8	8
CHEST PAIN PRECORDIAL	2	1	10	18	18
	1	2	2	2	2
INFLUENZA-LIKE SYMPTOMS	1	3	3	3	3
	1	1	1	1	1

(CONTINUED)

(*) adverse event present before start treatment; onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study; end date = visit date of last report visit

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 55

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)		
		Min	50%	Max
INFLUENZA-LIKE SYMPTOMS	1	5	5	5
ARTHRALGIA	1	3	3	3
BACK PAIN	1	6	6	6
HYPERTENSION	2	5	12	19
MYDRIASIS	1	2	2	2
CONJUNCTIVITIS	1	42	42	42
TINNITUS -	2	5	10	14
FLATULENCE	2	13	14	14
GAMMA-GT INCREASED	2	7	10	13
WEIGHT DECREASE	1	40	40	40
	1	12	12	12
	1	1	1	1
	1	8	8	8
	1	14	14	14
	1	19	19	19
	2	1	1	1
	1	3	3	3
	1	4	4	4
	1	6	6	6
	1	21	21	21
	1	4	4	4
	1	18	18	18

(CONTINUED)

(*) adverse event present before start treatment: onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study: end date = visit date of last report visit

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 55

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)		
		Min	50%	Max
MIGRAINE	1	2	2	2
SPEECH DISORDER	1	18	18	18
ANDREXIA	1	19	19	19
ACCOMMODATION ABNORMAL	1	14	14	14
FLUSHING	1	11	11	11
BRADYCARDIA	1	5	5	5
SALIVA INCREASED	1	20	20	20
CHROMATOPSIA	1	1	1	1
EYE ABNORMALITY	1	12	12	12
TASTE LOSS	1	22	22	22
TASTE PERVERSION	1	5	5	5
AUTOLESIONIST BEHAVIOUR	1	1	1	1
DEPERSONALIZATION	1	8	8	8
LIBIDO DECREASED	1	7	7	7
PARONIRIA	1	5	5	5
SLEEP DISORDER	1	45	45	45
DEPRESSION AGGRAVATED	1	2	2	2
CONCENTRATION IMPAIRED	1	20	20	20
COLITIS	1	5	5	5
DUODENAL ULCER REACTIVATED	1	15	15	15
DYSPHAGIA	1	19	19	19
GASTRITIS	1	2	2	2

(CONTINUED)

(*) adverse event present before start treatment: onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study: end date = visit date of last report visit

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 55

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)		
		Min	50%	Max
GASTROENTERITIS	1	6	6	6
TONGUE ULCERATION	1	8	8	8
TOOTH DISORDER	1	8	8	8
HYPERURICAEMIA	1	22	22	22
HYPOKALAEMIA	1	5	5	5
PHOSPHATASE ALKALINE INCREASED	1	1	1	1
HYPERTRIGLYCERIDAEMIA	1	30	30	30
EXTRASYSTOLES	1	3	3	3
HAEMORRHOIDS THROMBOSED	1	6	6	6
BRONCHITIS	1	6	6	6
ANAEMIA HYPOCHROMIC	1	2	2	2
EOSINOPHILIA	1	1	1	1
MICTURITION FREQUENCY	1	7	7	7
PYURIA	1	4	4	4
IMPOTENCE	1	32	32	32
PERINEAL PAIN MALE	1	35	35	35
EPIDIDYMITIS	1	32	32	32
MALaise	1	1	1	1
RIGORS	1	13	13	13
HYPERTYREXIA	1	2	2	2
PHARYNGITIS	1	8	8	8
HERPES SIMPLEX	1	6	6	6

(*) adverse event present before start treatment: onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study: end date = visit date of last report visit

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 56

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment																	
	Inipramine						Placebo						Reboxetine					
	Symptomatic treatment						Symptomatic treatment						Symptomatic treatment					
	YES	NO	Total		YES	NO	Total		YES	NO	Total		YES	NO	Total			
No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
No. of pt. with A.E.	22	27.2	59	72.8	81	100.0	15	25.9	43	74.1	58	100.0	24	33.8	47	66.2	71	100.0
No. of adverse events	30	10.4	258	89.6	288	100.0	23	16.3	118	83.7	141	100.0	40	19.0	171	81.0	211	100.0
MOUTH DRY	2	3.8	51	96.2	53	100.0	1	6.7	14	93.3	15	100.0	1	3.4	28	96.6	29	100.0
SWEATING INCREASED			26	100.0	26	100.0			3	100.0	3	100.0			15	100.0	15	100.0
CONSTIPATION	7	38.9	11	61.1	18	100.0	2	33.3	4	66.7	6	100.0	2	10.0	18	90.0	20	100.0
HEADACHE	5	55.6	4	44.4	9	100.0	2	20.0	8	80.0	10	100.0	6	33.3	12	66.7	18	100.0
NAUSEA	1	6.3	15	93.8	16	100.0			11	100.0	11	100.0	4	44.4	5	55.6	9	100.0
TREMOR			20	100.0	20	100.0			5	100.0	5	100.0			6	100.0	6	100.0
DIZZINESS			16	100.0	16	100.0			4	100.0	4	100.0			8	100.0	8	100.0
INSOMNIA	3	37.5	5	62.5	8	100.0	3	75.0	1	25.0	4	100.0	6	50.0	6	50.0	12	100.0
VISION ABNORMAL			10	100.0	10	100.0			3	100.0	3	100.0			7	100.0	7	100.0
AGITATION			4	100.0	4	100.0	1	14.3	6	85.7	7	100.0			8	100.0	8	100.0
SOMNOLENCE			6	100.0	6	100.0			10	100.0	10	100.0			1	100.0	1	100.0
VERTIGO			8	100.0	8	100.0							2	40.0	3	60.0	5	100.0
FATIGUE			4	100.0	4	100.0			4	100.0	4	100.0			3	100.0	3	100.0
PARAESTHESIA			6	100.0	6	100.0	1	50.0	1	50.0	2	100.0			2	100.0	2	100.0
SUICIDE ATTEMPT			4	100.0	4	100.0	2	50.0	2	50.0	4	100.0			1	100.0	1	100.0
ABDOMINAL PAIN	1	20.0	4	80.0	5	100.0			3	100.0	3	100.0			1	100.0	1	100.0
HYPOTENSION POSTURAL	2	33.3	4	66.7	6	100.0									2	100.0	2	100.0
TACHYCARDIA			4	100.0	4	100.0									3	100.0	3	100.0
DYSPNOEA			2	100.0	2	100.0							3	60.0	2	40.0	5	100.0

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 56

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment																										
	Imipramine									Placebo									Reboxetine								
	Symptomatic treatment									Symptomatic treatment									Symptomatic treatment								
	YES	NO	Total		YES	NO	Total		YES	NO	Total		YES	NO	Total		YES	NO	Total								
No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z								
RHINITIS	1	50.0	1	50.0	2	100.0	1	25.0	3	75.0	4	100.0			1	100.0	1	100.0	2	100.0							
HOT FLUSHES			4	100.0	4	100.0			1	100.0	4	100.0			1	100.0	2	100.0	2	100.0							
VOMITING			1	100.0	1	100.0			4	100.0	4	100.0			1	100.0	1	100.0	1	100.0							
DYSPEPSIA	2	40.0	3	60.0	5	100.0	1	100.0			1	100.0			1	100.0											
HYPOTENSION			1	100.0	1	100.0			2	100.0	2	100.0			1	50.0	1	50.0	2	100.0							
ANXIETY	1	100.0			1	100.0			3	100.0	3	100.0			1	100.0	1	100.0	1	100.0							
NERVOUSNESS									1	100.0	1	100.0			4	100.0	4	100.0	4	100.0							
MICTURITION DISORDER														1	100.0	1	100.0	3	100.0	3	100.0						
URINARY TRACT INFECTION														1	100.0	1	100.0	2	50.0	4	100.0						
PALPITATION			2	100.0	2	100.0			1	100.0	1	100.0			1	100.0	1	100.0	1	100.0							
ASTHENIA			3	100.0	3	100.0											1	100.0	1	100.0							
URINARY RETENTION									1	100.0	1	100.0			1	100.0	1	33.3	2	66.7							
RASH	1	100.0			1	100.0			2	100.0	2	100.0															
CONFUSION			2	100.0	2	100.0											1	100.0	1	100.0							
HYPERKINESIA			1	100.0	1	100.0			2	100.0	2	100.0															
MUSCLE CONTRACTIONS INVOLUNTARY			2	100.0	2	100.0											1	100.0	1	100.0							
DIARRHOEA											3	100.0															
APPETITE INCREASED			2	100.0	2	100.0					1	100.0															
WEIGHT INCREASE			2	100.0	2	100.0													1	100.0							
SINUSITIS									1	100.0	1	100.0					1	50.0	1	50.0							

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 56

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment																	
	Imipramine						Placebo						Reboxetine					
	Symptomatic treatment						Symptomatic treatment						Symptomatic treatment					
	YES	NO	Total	YES	NO	Total	YES	NO	Total	YES	NO	Total	YES	NO	Total			
No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z			
CHEST PAIN PRECORDIAL			2	100.0	2	100.0	1	100.0	1	100.0	1	100.0						
INFLUENZA-LIKE SYMPTOMS	1	100.0			1	100.0	1	100.0	1	100.0	1	100.0			1			
MYALGIA			1	100.0	1	100.0			2	100.0	2	100.0						
DYSURIA			1	100.0	1	100.0									2			
ARTHRALGIA									1	100.0	1	100.0			1			
BACK PAIN									2	100.0	2	100.0						
HYPERTENSION			1	100.0	1	100.0							1	100.0	1			
NYDRIASIS															2			
CONJUNCTIVITIS			2	100.0	2	100.0												
TINNITUS			2	100.0	2	100.0												
FLATULENCE									1	100.0	1	100.0			1			
GAMMA-GT INCREASED			1	100.0	1	100.0									1			
WEIGHT DECREASE															1			
SYNCOPE			2	100.0	2	100.0			1	100.0	1	100.0			1			
CHEST PAIN			1	100.0	1	100.0									1			
RASH ERYTHEMATOUS															1			
RHAGADES	1	100.0			1	100.0									1			
HYPERTONIA									1	100.0	1	100.0						
SPEECH DISORDER			1	100.0	1	100.0												
ANOREXIA															1			
ACCOMMODATION ABNORMAL			1	100.0	1	100.0												

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9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 56

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment																		
	Imipramine						Placebo						Reboxetine						
	Symptomatic treatment						Symptomatic treatment						Symptomatic treatment						
	YES	NO	Z	No.	%	Total	YES	NO	Z	No.	%	Total	YES	NO	Z	No.	%	Total	
FLUSHING																			
BRADYCARDIA									1	100.0	1	100.0						1	100.0
CHROMATOPSIA									1	100.0	1	100.0							
EYE ABNORMALITY																		1	100.0
TASTE LOSS									1	100.0	1	100.0							
TASTE PERVERSION																			
AUTOLESIONIST BEHAVIOUR									1	100.0	1	100.0							
DEPERSONALIZATION									1	100.0	1	100.0							
PARONIRIA													1	100.0				1	100.0
SLEEP DISORDER									1	100.0	1	100.0							
DEPRESSION AGGRAVATED																			
CONCENTRATION IMPAIRED									1	100.0	1	100.0							
DUODENAL ULCER REACTIVATED	1	100.0				1	100.0												
GASTRITIS																			
GASTROENTERITIS																		1	100.0
TOOTH DISORDER																		1	100.0
HYPOKALAEMIA									1	100.0	1	100.0							
PHOSPHATASE ALKALINE INCREASED									1	100.0	1	100.0							
HYPERTIGLYCERIDAEMIA									1	100.0	1	100.0							
EXTRASYSTOLES									1	100.0	1	100.0							

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 56

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment																		
	Imipramine						Placebo						Reboxetine						
	Symptomatic treatment			Total			Symptomatic treatment			Total			Symptomatic treatment			Total			
	YES	NO	Z	No.	Z	%	YES	NO	Z	No.	Z	%	YES	NO	Z	No.	Z	%	
HAEMORRHOIDS THROMBOSED																			
BRONCHITIS																			
ANAEMIA HYPOCHROMIC	1	100.0		1	100.0														
EOSINOPHILIA																			
PYURIA																			
HYPERPYREXIA																			
HERPES SIMPLEX																			
COLD URTICARIA																			
MIGRAINE																			
SALIVA INCREASED																			
LIBIDO DECREASED																			
COLITIS																			
DYSPHAGIA																			
TONGUE ULCERATION																			
HYPERURICAEMIA																			
NICTURITION FREQUENCY																			
IMPOTENCE																			
PERINEAL PAIN MALE																			
EPIDIDYMITIS																			
MALAISE																			
RIGORS																			

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 57

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Study drug																		
	No change			Dose reduced			Temporarily interrupted			Definitively withdrawn			Missing			Total			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
All adverse events	Imipramine	235	81.6	6	2.1	5	1.7	30	10.4	12	4.2	288	100.0						
	Placebo	125	88.7			2	1.4	12	8.5	2	1.4	141	100.0						
	Reboxetine	181	85.8	4	1.9			20	9.5	6	2.8	211	100.0						
MOUTH DRY	Imipramine	49	92.5	1	1.9			2	3.8	1	1.9	53	100.0						
	Placebo	13	86.7			1	6.7	1	6.7			15	100.0						
	Reboxetine	27	93.1	1	3.4			1	3.4			29	100.0						
NAUSEA AND RELATED SYMPTOMS	Imipramine	15	68.2	1	4.5	1	4.5	3	13.6	2	9.1	22	100.0						
	Placebo	15	93.8					1	6.3			16	100.0						
	Reboxetine	11	100.0									11	100.0						
SWEATING INCREASED	Imipramine	21	80.8					4	15.4	1	3.8	26	100.0						
	Placebo	3	100.0									3	100.0						
	Reboxetine	13	86.7					1	6.7	1	6.7	15	100.0						
CONSTIPATION	Imipramine	16	88.9	1	5.6					1	5.6	18	100.0						
	Placebo	6	100.0									6	100.0						
	Reboxetine	19	95.0					1	5.0			20	100.0						
HYPOTENSION AND RELATED SYMPTOMS	Imipramine	20	80.0	1	4.0	1	4.0	3	12.0			25	100.0						
	Placebo	6	100.0									6	100.0						
	Reboxetine	9	75.0					2	16.7	1	8.3	12	100.0						
HEADACHE / MIGRAINE	Imipramine	7	77.8					1	11.1	1	11.1	9	100.0						
	Placebo	10	100.0									10	100.0						
	Reboxetine	19	100.0									19	100.0						

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 57

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Study drug																	
	No change			Dose reduced			Temporarily interrupted			Definitively withdrawn			Missing			Total		
	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%
TREMOR	Imipramine	17	85.0	1	5.0				2	10.0					20	100.0		
	Placebo	5	100.0												5	100.0		
	Reboxetine	5	83.3	1	16.7										6	100.0		
AGITATION / ANXIETY / NERVOUSNESS	Imipramine	4	80.0			1	20.0								5	100.0		
	Placebo	7	63.6			1	9.1		3	27.3					11	100.0		
	Reboxetine	10	76.9	1	7.7				2	15.4					13	100.0		
INSOMNIA	Imipramine	4	50.0	1	12.5										5	100.0		
	Placebo	3	75.0												3	100.0		
	Reboxetine	9	75.0						2	16.7					11	100.0		
BLURRED VISION	Imipramine	9	81.8						2	18.2					11	100.0		
	Placebo	3	100.0												3	100.0		
	Reboxetine	6	85.7										1	14.3	7	100.0		
SOMNOLENCE	Imipramine	6	100.0												6	100.0		
	Placebo	10	100.0												10	100.0		
	Reboxetine	1	100.0												1	100.0		
ASTHENIA / FATIGUE	Imipramine	7	100.0												7	100.0		
	Placebo	4	100.0												4	100.0		
	Reboxetine	4	100.0												4	100.0		
VERTIGO	Imipramine	6	75.0						2	25.0					8	100.0		
	Reboxetine	3	60.0						2	40.0					5	100.0		
	Imipramine	5	83.3										1	16.7	6	100.0		

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 57

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Study drug															
	No change			Dose reduced			Temporarily interrupted			Definitively withdrawn			Missing		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
PARAESTHESIA	Placebo	2	100.0												2	100.0
	Reboxetine	1	50.0					1	50.0						2	100.0
ABDOMINAL PAIN	Imipramine	4	80.0					1	20.0						5	100.0
	Placebo	3	100.0												3	100.0
SUICIDE ATTEMPT	Reboxetine	1	100.0												1	100.0
	Imipramine	1	25.0					3	75.0						4	100.0
	Placebo	2	50.0					2	50.0						4	100.0
	Reboxetine							1	100.0						1	100.0
URINARY HESITANCY / RETENTION	Imipramine	1	100.0												1	100.0
	Placebo	2	100.0												2	100.0
	Reboxetine	5	83.3					1	16.7						6	100.0
	Imipramine	2	50.0					1	25.0						4	100.0
FLUSHING / HOT FLUSHES	Placebo	1	100.0												1	100.0
	Reboxetine	3	100.0												3	100.0
TACHYCARDIA	Imipramine	2	50.0					1	25.0			1	25.0	4	100.0	
	Reboxetine	2	66.7					1	33.3					3	100.0	
DYSPNOEA	Imipramine	2	100.0												2	100.0
	Reboxetine	5	100.0												5	100.0
RHINITIS	Imipramine	2	100.0												2	100.0
	Placebo	4	100.0												4	100.0
	Reboxetine	1	100.0												1	100.0

(CONTINUED)

(Some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 57

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Study drug											
	No change		Dose reduced		Temporarily interrupted		Definitively withdrawn		Missing		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
URINARY TRACT INFECTION	Placebo	1	100.0								1	100.0
	Reboxetine	3	75.0			1	25.0				4	100.0
	Imipramine	2	100.0								2	100.0
PALPITATION	Placebo	1	100.0								1	100.0
	Reboxetine	1	100.0								1	100.0
	Imipramine	1	100.0								1	100.0
ERYTHEMA / RASH	Placebo	1	50.0					1	50.0		2	100.0
	Reboxetine	1	100.0								1	100.0
	Imipramine	1	50.0								1	100.0
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Placebo	1	100.0								1	100.0
	Reboxetine	1	100.0								1	100.0
	Imipramine	1	50.0					1	50.0		2	100.0
CONFUSION	Placebo	1	100.0								1	100.0
	Reboxetine	1	50.0						1	50.0	2	100.0
	Imipramine	1	100.0								1	100.0
HYPERKINESIA	Placebo	1	100.0								1	100.0
	Reboxetine	1	50.0								1	100.0
	Imipramine	2	100.0								2	100.0
MUSCLE CONTRACTIONS INVOLUNTARY	Placebo	1	100.0								1	100.0
	Reboxetine	1	100.0								1	100.0
	Imipramine	2	100.0								2	100.0
APPETITE INCREASED	Placebo	2	100.0								2	100.0
	Reboxetine	1	100.0								1	100.0
	Imipramine	2	66.7					1	33.3		3	100.0
WEIGHT INCREASE	Placebo	2	100.0								2	100.0
	Reboxetine	1	100.0								1	100.0
	Imipramine	1	100.0								1	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 57

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Study drug												
	No change		Dose reduced		Temporarily interrupted		Definitively withdrawn		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
MYALGIA	1	100.0									1	100.0	
	2	100.0									2	100.0	
SINUSITIS	1	100.0									1	100.0	
	2	100.0									2	100.0	
DYSURIA	1	100.0									1	100.0	
	2	100.0									2	100.0	
INFLUENZA-LIKE SYMPTOMS										1	100.0	1	100.0
										1	100.0	1	100.0
CHEST PAIN	1	100.0									1	100.0	
HYPERTENSION	1	100.0									1	100.0	
	1	100.0									1	100.0	
FLATULENCE	1	100.0									1	100.0	
	1	100.0									1	100.0	
TINNITUS	1	50.0					1	50.0			2	100.0	
	1	100.0									1	100.0	
WEIGHT DECREASE	1	100.0									1	100.0	
	1	100.0									1	100.0	
ARTHRALGIA	1	100.0									1	100.0	
	1	100.0									1	100.0	

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 57

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Study drug																
	No change			Dose reduced			Temporarily interrupted			Definitively withdrawn			Missing		Total		
	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	No.	Z	
ARTHRALGIA																	
BACK PAIN																	
CONJUNCTIVITIS																	
HYDRALASIS																	
SALIVA INCREASED																	
HYPERTREXIA																	
MALISE																	
RIGORS																	
EXTRASYSTOLES																	
HYPERTONIA																	
SPEECH DISORDER																	
ANOREXIA																	
DUODENAL ULCER REACTIVATED																	
GASTROENTERITIS																	
TONGUE ULCERATION																	
ANEMIA																	
EOSINOPHILIA																	
HYPERTRIGLICERIDAEMIA																	
HYPERTURICAEMIA																	
HYPOKALAEMIA																	
PHOSPHATASE ALKALINE INCREASED																	

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 57

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Study drug											
	No change		Dose reduced		Temporarily interrupted		Definitively withdrawn		Missing		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
CONCENTRATION IMPAIRED	1	100.0									1	100.0
DEPERSONALIZATION	1	100.0									1	100.0
LIBIDO DECREASED	1	100.0									1	100.0
PARONYCHIA	1	100.0									1	100.0
SLEEP DISORDER	1	100.0									1	100.0
EPIDIDYMITIS	1	100.0									1	100.0
PERINEAL PAIN MALE	1	100.0									1	100.0
HERPES SIMPLEX	1	100.0									1	100.0
BRONCHITIS	1	100.0									1	100.0
PHARYNGITIS	1	100.0									1	100.0
COLD URTICARIA	1	100.0									1	100.0
RHAGADES	1	100.0									1	100.0
TASTE LOSS	1	100.0									1	100.0
TASTE PERVERSION	1	100.0									1	100.0
MICTURITION FREQUENCY	1	100.0									1	100.0
PYURIA	1	100.0									1	100.0
CHROMATOPSIA	1	100.0									1	100.0
EYE ABNORMALITY	1	100.0									1	100.0
AUTOLESIONIST BEHAVIOUR					1	100.0					1	100.0
BRADYCARDIA											1	100.0
HAEMORRHOIDS THROBUSED											1	100.0

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(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 57

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Study drug																	
	No change			Dose reduced			Temporarily interrupted			Definitively withdrawn			Missing			Total		
	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z		
COLITIS													1	100.0			1	100.0
DYSPHAGIA													1	100.0			1	100.0
DEPRESSION AGGRAVATED													1	100.0			1	100.0
IMPOTENCE													1	100.0			1	100.0
TOOTH DISORDER															1	100.0	1	100.0

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 58

ADVERSE EVENTS: DISAPPEARED AFTER ACTION ON STUDY DRUG AND REAPPEARED ON RESUMING TREATMENT BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	Modified study drug												Temporarily interrupted												
	Disappeared						Reappeared						YES			NO			Not applicable			Total			
	YES		NO		Not applicable		Total		YES		NO		Not applicable		Total		YES		NO		Not applicable		Total		
No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z		
All adverse events	1	7.1	11	78.6	2	14.3	14	100.0																	
	12	50.0	12	50.0			24	100.0																	
	18	43.9	12	29.3	11	26.8	41	100.0																	
AGITATION / ANXIETY / NERVOUSNESS	1	33.3	2	66.7			3	100.0																	
MOUTH DRY																									
	1	50.0	1	50.0			2	100.0																	
	2	66.7																							
HYPOTENSION AND RELATED SYMPTOMS	1	50.0	1	50.0																					
	1	20.0	3	60.0	1	20.0	5	100.0																	
NAUSEA AND RELATED SYMPTOMS	2	40.0	1	20.0	2	40.0	5	100.0																	
SUICIDE ATTEMPT	1	100.0																							
SWEATING INCREASED	1	25.0	3	75.0																					
	1	100.0																							
TREMOR																									
	1	33.3	2	66.7			3	100.0																	

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 56

ADVERSE EVENTS: DISAPPEARED AFTER ACTION ON STUDY DRUG AND REAPPEARED ON RESUMING TREATMENT BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	Modified study drug												Temporarily interrupted											
	Disappeared						Reappeared						NO			YES			Not applicable			Total		
	YES		NO		Not applicable		NO		NO		NO		YES		NO		YES		Not applicable		Total			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%		
VERTIGO	Reboxetine	1	50.0	1	50.0																			
	Imipramine	1	50.0	1	50.0																			
INSOMNIA	Reboxetine	2	100.0																					
	Imipramine	1	50.0			1	50.0																	
FLUSHING / HOT FLUSHES	Imipramine	1	50.0			1	50.0																	
	Reboxetine			1	100.0																			
TACHYCARDIA	Imipramine			1	100.0																			
	Reboxetine	1	100.0																					
CONSTIPATION	Reboxetine	1	100.0																					
	Imipramine	1	100.0																					
BLURRED VISION	Imipramine	1	50.0	1	50.0																			
	Reboxetine			1	100.0																			
CHEST PAIN	Reboxetine			1	100.0																			
	Placebo			1	100.0																			
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Imipramine					1	100.0																	
	Reboxetine	1	100.0																					
HAEMORRHOIDS THROMBOSED	Reboxetine							1	100.0															
	Reboxetine	1	100.0																					
HEADACHE / MIGRAINE	Imipramine	1	100.0																					
	Placebo			1	100.0																			
MUSCLE CONTRACTIONS INVOLUNTARY	Reboxetine	1	100.0																					
	Reboxetine			1	100.0																			

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 56

ADVERSE EVENTS: DISAPPEARED AFTER ACTION ON STUDY DRUG AND REAPPEARED ON RESUMING TREATMENT BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	Modified study drug																
	Disappeared						Temporarily interrupted										
	YES		NO		Not applicable		Total		YES		NO		Not applicable		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
ABDOMINAL PAIN	1	100.0					1	100.0									
ADLITIS	1	100.0					1	100.0									
DIARRHOEA			1	100.0			1	100.0									
DYSPHAGIA	1	100.0					1	100.0									
TINNITUS	1	100.0					1	100.0									
AUTOLESIONIST BEHAVIOUR							1	100.0						1	100.0	1	100.0
DEPRESSION AGGRAVATED	1	100.0					1	100.0									
IMPOTENCE			1	100.0			1	100.0									
ERYTHEMA / RASH			1	100.0			1	100.0									
URINARY HESITANCY / RETENTION			1	100.0			1	100.0									
URINARY TRACT INFECTION	1	100.0					1	100.0									

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Modified study drug										Unchanged study drug or Missing												
	Recovered with sequelae		Still present		Death		Missing		Total		Recovered with sequelae		Still present		Death		Missing		Total				
	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z			
ALL adverse events	Placebo	9	64.3	1	7.1	4	28.6			14	100	80	63.0					4	3.1	127	100		
	Reboxetine	7	29.2			17	70.8			24	100	104	55.6					13	7.0	187	100		
	Imipramine	15	36.6			25	61.0		1	2.4	41	100	116	47.0			1	0.4	15	6.1	247	100	
MOUTH DRY	Placebo	2	100							2	100	8	61.5					1	7.7	13	100		
	Reboxetine	1	50.0			1	50.0			2	100	7	25.9					1	3.7	27	100		
	Imipramine					3	100			3	100	17	34.0					2	4.0	50	100		
NAUSEA AND RELATED SYMPTOMS	Placebo	1	100							1	100	14	93.3								15	100	
	Reboxetine											9	81.8								11	100	
	Imipramine	2	40.0			3	60.0			5	100	12	70.6					1	5.9	17	100		
SWEATING INCREASED	Placebo											1	33.3								3	100	
	Reboxetine					1	100			1	100	8	57.1							3	21.4	14	100
	Imipramine	3	75.0			1	25.0			4	100	13	59.1					1	4.5	22	100		
CONSTIPATION	Placebo											2	33.3								6	100	
	Reboxetine					1	100			1	100	7	36.8								19	100	
	Imipramine					1	100			1	100	5	29.4					1	5.9	17	100		
HYPERTENSION AND RELATED SYMPTOMS	Placebo											5	83.3								6	100	
	Reboxetine					2	100			2	100	6	60.0							2	20.0	10	100
	Imipramine	1	20.0			4	80.0			5	100	14	70.0					1	5.0	20	100		
HEADACHE / MIGRAINE	Placebo											8	80.0								10	100	
	Reboxetine											15	78.9								19	100	

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CMS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Modified study drug										Unchanged study drug or Missing												
	Recovered with sequelae		Still present		Death		Missing		Total		Recovered		Recovered with sequelae		Still present		Death		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
HEADACHE / MIGRAINE	Imipramine			1	100					1	100	3	37.5			5	52.5					8	100
	Placebo											4	80.0			1	20.0					5	100
	Reboxetine			1	100					1	100	5	100									5	100
TREMOR	Imipramine	1	33.3	2	66.7					3	100	8	47.1			8	47.1			1	5.9	17	100
	Placebo	2	50.0	2	50.0					4	100	5	71.4			2	28.6					7	100
	Reboxetine	1	33.3	2	66.7					3	100	4	40.0			6	60.0					10	100
AGITATION / ANXIETY / NERVOUSNESS	Imipramine	1	100							1	100	2	50.0			2	50.0					4	100
	Placebo											1	25.0			2	50.0			1	25.0	4	100
	Reboxetine			2	100					2	100	4	40.0			4	40.0			2	20.0	10	100
INSOMNIA	Imipramine			2	100					2	100					4	66.7			2	33.3	6	100
	Placebo														3	100					3	100	
	Reboxetine											4	57.1			2	28.6			1	14.3	7	100
BLURRED VISION	Imipramine	1	50.0							2	100	5	55.6			3	33.3			1	11.1	9	100
	Placebo										4	40.0			6	60.0					10	100	
	Reboxetine														1	100					1	100	
SOMNOLENCE	Imipramine																						
	Placebo																						
	Reboxetine																						
ASTHENIA / FATIGUE	Imipramine																						
	Placebo																						
	Reboxetine																						
VERTIGO	Imipramine																						
	Placebo																						
	Reboxetine	1	50.0							2	100	2	66.7			1	33.3					3	100

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Modified study drug										Unchanged study drug or Missing												
	Recovered		Still present		Death		Missing		Total		Recovered		Recovered with sequelae		Still present		Death		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
INCREASED LIVER ENZYMES	Reboxetine																						
	Imipramine																						
WEIGHT DECREASE	Placebo																						
	Reboxetine																						
ARTHRALGIA	Placebo																						
	Reboxetine																						
BACK PAIN	Placebo																						
	Imipramine																						
CONJUNCTIVITIS	Reboxetine																						
	Reboxetine																						
HYDRALASIS	Reboxetine																						
	Reboxetine																						
SALIVA INCREASED	Reboxetine																						
	Reboxetine																						
HYPERPYREXIA	Placebo																						
	Imipramine																						
RIGORS	Placebo																						
	Imipramine																						
BRADYCARDIA	Placebo	1	100							1	100												
	Imipramine																						
EXTRASYSTOLES	Reboxetine																						
	Reboxetine																						
HAEMORRHOIDS THROMBOSED	Placebo																						
	Imipramine																						
HYPERTONIA	Placebo																						
	Imipramine																						
SPEECH DISORDER	Reboxetine																						
	Reboxetine																						
ANOREXIA	Reboxetine																						
	Imipramine																						
COLITIS	Reboxetine																						
	Imipramine																						

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Modified study drug										Unchanged study drug or Missing													
	Recovered with sequelae		Still present		Death		Missing		Total		Recovered		Recovered with sequelae		Still present		Death		Missing		Total			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%		
377																								
DUODENAL ULCER REACTIVATED																								
DYSPHAGIA				1	100																			
GASTROENTERITIS																								
TONGUE ULCERATION																								
TONGUE ULCERATION																								
TOOTH DISORDER																								
ANEMIA																								
EOSINOPHILIA																								
HYPERTRIGLYCERID- AEMIA																								
HYPERURIC AEMIA																								
HYPERURIC AEMIA																								
HYPOKALAEMIA																								
PHOSPHATASE ALKALINE INCREASED																								
AUTOLESIONIST BEHAVIOUR																								
CONCENTRATION IMPAIRED																								
DEPERSONALIZATION																								
DEPRESSION AGGRAVATED																								
LIBIDO DECREASED																								
PANORRRIA																								

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	All adverse events													
	Recovered		Recovered with sequelae		Still present		Death		Missing		Total			
	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z		
All adverse events	Placabo	89	63.1	1	0.7	47	33.3			4	2.8	141	100.0	
	Reboxetine	111	52.6			87	41.2			13	6.2	211	100.0	
	Imipramine	131	45.5			140	48.6	1	0.3	16	5.6	288	100.0	
MOUTH DRY	Placabo	10	66.7			4	26.7			1	6.7	15	100.0	
	Reboxetine	8	27.6			20	69.0			1	3.4	29	100.0	
	Imipramine	17	32.1			34	64.2			2	3.8	53	100.0	
NAUSEA AND RELATED SYMPTOMS	Placabo	15	93.8			1	6.3					16	100.0	
	Reboxetine	9	81.8			2	18.2					11	100.0	
	Imipramine	14	63.6			7	31.8			1	4.5	22	100.0	
SWEATING INCREASED	Placabo	1	33.3			2	66.7					3	100.0	
	Reboxetine	8	53.3			4	26.7			3	20.0	15	100.0	
	Imipramine	16	61.5			9	34.6			1	3.8	26	100.0	
CONSTIPATION	Placabo	2	33.3			4	66.7					6	100.0	
	Reboxetine	7	35.0			13	65.0					20	100.0	
	Imipramine	5	27.8			12	66.7			1	5.6	18	100.0	
HYPOTENSION AND RELATED SYMPTOMS	Placabo	5	83.3			1	16.7					6	100.0	
	Reboxetine	6	50.0			4	33.3			2	16.7	12	100.0	
	Imipramine	15	60.0			9	36.0			1	4.0	25	100.0	
HEADACHE / MIGRAINE	Placabo	8	80.0			2	20.0					10	100.0	
	Reboxetine	15	78.9			4	21.1					19	100.0	

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	All adverse events																			
	Recovered			Recovered with sequelae			Still present			Death			Missing			Total				
	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%		
HEADACHE / MIGRAINE	Imipramine	3	33.3			6	66.7											9	100.0	
	Placebo	4	80.0			1	20.0												5	100.0
TREMOR	Reboxetine	5	83.3			1	16.7												6	100.0
	Imipramine	9	45.0			10	50.0						1	5.0					20	100.0
AGITATION / ANXIETY / NERVOUSNESS	Placebo	7	63.6			4	36.4												11	100.0
	Reboxetine	5	38.5			8	61.5												13	100.0
IMIPRAMINE	Imipramine	3	60.0			2	40.0												5	100.0
	Placebo	1	25.0			2	50.0						1	25.0					4	100.0
INSOMNIA	Reboxetine	4	33.3			6	50.0						2	16.7					12	100.0
	Imipramine					6	75.0						2	25.0					8	100.0
BLURRED VISION	Placebo					3	100.0												3	100.0
	Reboxetine	4	57.1			2	28.6						1	14.3					7	100.0
SOMNOLENCE	Imipramine	6	54.5			4	36.4						1	9.1					11	100.0
	Placebo	4	40.0			6	60.0												10	100.0
ASTHENTIA / FATIGUE	Reboxetine					1	100.0												1	100.0
	Imipramine	4	66.7			1	16.7						1	16.7					6	100.0
ASTHENTIA / FATIGUE	Placebo	2	50.0			2	50.0												4	100.0
	Reboxetine	2	50.0			2	50.0												4	100.0
VERTIGO	Imipramine	1	14.3			6	85.7												7	100.0
	Reboxetine	3	60.0			2	40.0												5	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	All adverse events												
	Recovered		Recovered with sequelae		Still present		Death		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
VERTIGO	Imipramine	7	87.5			1	12.5					8	100.0
	Placebo	2	100.0									2	100.0
PARAESTHESIA	Reboxetine	1	50.0			1	50.0					2	100.0
	Imipramine	3	50.0			2	33.3			1	16.7	6	100.0
ABDOMINAL PAIN	Placebo	2	66.7			1	33.3					3	100.0
	Reboxetine	1	100.0									1	100.0
SUICIDE ATTEMPT	Imipramine	3	60.0			2	40.0					5	100.0
	Placebo	2	50.0	1	25.0	1	25.0					4	100.0
URINARY HESITANCY / RETENTION	Reboxetine					1	100.0					1	100.0
	Imipramine	1	25.0			1	25.0	1	25.0	1	25.0	4	100.0
FLUSHING / HOT FLUSHES	Placebo	1	50.0			1	50.0					2	100.0
	Reboxetine	4	66.7			2	33.3					6	100.0
TACHYCARDIA	Imipramine					1	100.0					1	100.0
	Placebo	1	100.0									1	100.0
DYSPNOEA	Reboxetine	2	66.7			1	33.3					3	100.0
	Imipramine	3	75.0			1	25.0					4	100.0
	Reboxetine	3	75.0							1	25.0	4	100.0
	Imipramine	4	80.0			1	20.0					5	100.0
	Imipramine	2	100.0									2	100.0

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(some adverse events are grouped in cluster)

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PHARMACIA CNS R2D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	All adverse events												
	Recovered		Recovered with sequelae		Still present		Death		Missing		Total		
	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	
RHINITIS	Placebo	3	75.0							1	25.0	4	100.0
	Reboxetine	1	100.0									1	100.0
	Imipramine					2	100.0					2	100.0
URINARY TRACT INFECTION	Placebo					1	100.0					1	100.0
	Reboxetine	2	50.0			2	50.0					4	100.0
PALPITATION	Placebo	1	100.0									1	100.0
	Reboxetine	1	100.0									1	100.0
	Imipramine	1	50.0			1	50.0					2	100.0
ERYTHEMA / RASH	Placebo	2	100.0									2	100.0
	Reboxetine					1	100.0					1	100.0
	Imipramine					1	100.0					1	100.0
INFLUENZA-LIKE SYMPTOMS	Placebo									1	100.0	1	100.0
	Reboxetine									1	100.0	1	100.0
	Imipramine									1	100.0	1	100.0
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Placebo	1	100.0									1	100.0
	Imipramine	2	100.0									2	100.0
CONFUSION	Reboxetine	1	100.0									1	100.0
	Imipramine	1	50.0							1	50.0	2	100.0
HYPERKINESIA	Placebo					2	100.0					2	100.0
	Imipramine					1	100.0					1	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	All adverse events												
	Recovered		Recovered with sequelae		Still present		Death		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
MUSCLE CONTRACTIONS INVOLUNTARY	Reboxetine					1	100.0					1	100.0
	Imipramine	1	50.0			1	50.0					2	100.0
APPETITE INCREASED	Placebo	1	100.0									1	100.0
	Imipramine					2	100.0					2	100.0
DIARRHOEA	Placebo	2	66.7			1	33.3					3	100.0
WEIGHT INCREASE	Reboxetine					1	100.0					1	100.0
	Imipramine					2	100.0					2	100.0
MYALGIA	Placebo	1	50.0			1	50.0					2	100.0
	Imipramine	1	100.0									1	100.0
SINUSITIS	Placebo	1	100.0									1	100.0
	Reboxetine	2	100.0									2	100.0
DYSURIA	Reboxetine	2	100.0									2	100.0
	Imipramine	1	100.0									1	100.0
CHEST PAIN	Reboxetine					1	100.0					1	100.0
	Imipramine	1	100.0									1	100.0
HYPERTENSION	Reboxetine					1	100.0					1	100.0
	Imipramine	1	100.0									1	100.0
FLATULENCE	Placebo					1	100.0					1	100.0
	Reboxetine					1	100.0					1	100.0
TINNITUS	Imipramine	1	50.0			1	50.0					2	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	All adverse events											
	Recovered		Recovered with sequelae		Still present		Death		Missing		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
INCREASED LIVER ENZYMES												
WEIGHT DECREASE												
ARTHRALGIA												
BACK PAIN												
CONJUNCTIVITIS												
HYDRASIS												
SALIVA INCREASED												
HYPERPYREXIA												
MALaise												
RIGORS												
BRADYCARDIA												
EXTRASYSTOLES												
HAEMORRHOIDS THROMBOSED												
HYPERTONIA												
SPEECH DISORDER												
ANOREXIA												
COLITIS												

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	All adverse events												
	Recovered		Recovered with sequelae		Still present		Death		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
DUODENAL ULCER REACTIVATED					1	100.0						1	100.0
DYSPHAGIA					1	100.0						1	100.0
GASTROENTERITIS	1	100.0										1	100.0
TONGUE ULCERATION	1	100.0										1	100.0
TOOTH DISORDER									1	100.0		1	100.0
ANEMIA					1	100.0						1	100.0
EOSINOPHILIA					1	100.0						1	100.0
HYPERTRIGLYCERIDAEMIA					1	100.0						1	100.0
HYPERURICAEMIA	1	100.0										1	100.0
HYPOKALAEMIA	1	100.0										1	100.0
PHOSPHATASE ALKALINE INCREASED					1	100.0						1	100.0
AUTOLESIONIST BEHAVIOUR	1	100.0										1	100.0
CONCENTRATION IMPAIRED					1	100.0						1	100.0
DEPERSONALIZATION					1	100.0						1	100.0
DEPRESSION AGGRAVATED					1	100.0						1	100.0
LIBIDO DECREASED										1	100.0	1	100.0
PARONYCHIA					1	100.0						1	100.0
SLEEP DISORDER					1	100.0						1	100.0
EPIDIDYMITIS	1	100.0										1	100.0
IMPOTENCE	1	100.0										1	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 59

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	All adverse events												
	Recovered		Recovered with sequelae		Still present		Death		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
PERINEAL PAIN MALE	1	100.0										1	100.0
HERPES SIMPLEX	1	100.0										1	100.0
BRONCHITIS	1	100.0										1	100.0
PHARYNGITIS	1	100.0										1	100.0
COLD URTICARIA					1	100.0						1	100.0
RHAGADES	1	100.0										1	100.0
TASTE LOSS	1	100.0										1	100.0
TASTE PERVERSION					1	100.0						1	100.0
MICTURITION FREQUENCY					1	100.0						1	100.0
PYURIA					1	100.0						1	100.0
CHROMATOPSIA	1	100.0										1	100.0
EYE ABNORMALITY	1	100.0										1	100.0

(some adverse events are grouped in cluster)

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment																				
		0-7		8-14		15-21		22-28		29-35		36-42		> 42								
		No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)							
Pt exposed	Imipramine	115	100	2.33	107	100	2.70	96	100	2.73	89	100	2.46	85	100	2.46	17	100	2.42			
	Placebo	112	100	1.62	107	100	1.68	102	100	1.67	97	100	1.75	89	100	1.92	87	100	1.78	23	100	1.81
	Reboxetine	112	100	2.10	106	100	2.24	102	100	2.22	98	100	2.19	93	100	1.97	90	100	1.84	14	100	1.47
MOUTH DRY	Imipramine	33	28.7	1.00	37	34.6	1.00	33	34.4	1.00	32	36.0	1.00	27	31.8	1.00	26	32.1	1.00	14	82.4	1.00
	Placebo	8	7.1	1.00	7	6.5	1.00	9	8.8	1.00	10	10.3	1.00	8	9.0	1.00	5	5.7	1.00	3	13.0	1.00
	Reboxetine	17	15.2	1.00	22	20.8	1.04	22	21.6	1.04	19	19.4	1.05	16	17.2	1.00	14	15.6	1.00	8	57.1	1.00
CONSTIPATION	Imipramine	5	4.3	1.00	12	11.2	1.00	14	14.6	1.00	12	13.5	1.00	12	14.1	1.00	12	14.8	1.00	9	52.9	1.00
	Placebo	1	0.9	1.00	4	3.7	1.00	3	2.9	1.00	3	3.1	1.00	4	4.5	1.00	4	4.6	1.00	2	8.7	1.00
	Reboxetine	7	6.3	1.00	14	13.2	1.00	13	12.7	1.00	12	12.2	1.00	10	10.8	1.00	9	10.0	1.00	4	28.6	1.00
SWEATING INCREASED	Imipramine	15	13.0	1.00	17	15.9	1.00	9	9.4	1.00	11	12.4	1.00	9	10.6	1.00	9	11.1	1.00	4	23.5	1.25
	Placebo	2	1.8	1.00	2	1.9	1.00	2	2.0	1.00	2	2.1	1.00	2	2.2	1.00	2	2.3	1.00	2	8.7	1.00
	Reboxetine	7	6.3	1.00	11	10.4	1.00	9	8.8	1.11	9	9.2	1.00	5	5.4	1.00	4	4.4	1.00	1	7.1	1.00
TREMOR	Imipramine	6	5.2	1.00	12	11.2	1.00	16	16.7	1.00	13	14.6	1.00	11	12.9	1.00	8	9.9	1.00	4	23.5	1.00
	Placebo	4	3.6	1.00	3	2.8	1.00							1	1.1	1.00						
	Reboxetine	4	3.6	1.00	3	2.8	1.00	3	2.9	1.00	1	1.0	1.00	1	1.1	1.00						
HEADACHE	Imipramine	4	3.5	1.00	5	4.7	1.00	3	3.1	1.00	4	4.5	1.00	2	2.4	1.00	2	2.5	1.00	1	5.9	1.00
	Placebo	3	2.7	1.00	4	3.7	1.00	5	4.9	1.00	4	4.1	1.00	4	4.5	1.00	3	3.4	1.00	1	4.3	1.00
	Reboxetine	10	8.9	1.00	8	7.5	1.12	5	4.9	1.00	6	6.1	1.00	4	4.3	1.00	3	3.3	1.00	2	14.3	1.00
NAUSEA	Imipramine	6	5.2	1.00	8	7.5	1.00	7	7.3	1.00	5	5.6	1.00	1	1.2	1.00	3	3.7	1.00	2	11.8	1.00
	Placebo	3	2.7	1.00	4	3.7	1.00	3	2.9	1.00	4	4.1	1.00	3	3.4	1.00	1	1.1	1.00			

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment																							
		0-7		8-14		15-21		22-28		29-35		36-42		> 42											
		No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)										
NAUSEA	Reboxetine	6	5.4	3	2.8	1.00	5	4.9	1.00	4	4.1	1.00	3	3.2	1.00	2	2.2	1.00	1	7.1	1.00				
	Imipramine	4	3.5	1.00	5	4.7	1.00	4	4.2	1.00	3	3.4	1.00	4	4.7	1.00	3	3.7	1.00	2	11.8	1.00			
	Placebo	2	1.8	1.00	2	1.9	1.00	1	1.0	1.00	2	2.1	1.00	2	2.2	1.00	2	2.3	1.00	1	4.3	1.00			
VISTON ABNORMAL	Reboxetine	6	5.4	1.00	5	4.7	1.00	6	5.9	1.00	4	4.1	1.00	4	4.3	1.00	5	5.6	1.00	1	7.1	1.00			
	Imipramine	3	2.6	1.00	6	5.6	1.00	5	5.2	1.00	5	5.6	1.00	6	7.1	1.00	5	6.2	1.00	4	23.5	1.00			
	Placebo				3	2.8	1.00	3	2.9	1.00	3	3.1	1.00	3	3.4	1.00	3	3.4	1.00	2	8.7	1.00			
DIZZINESS	Reboxetine	3	2.7	1.00	3	2.8	1.00	3	2.9	1.00	3	3.1	1.00	3	3.2	1.00	3	3.2	1.00	1	1.1	1.00			
	Imipramine	6	5.2	1.00	9	8.4	1.00	7	7.3	1.00	6	6.7	1.00	3	3.5	1.00	3	3.7	1.00	2	11.8	1.00			
	Placebo	1	0.9	1.00	1	0.9	1.00	3	2.9	1.00	2	2.1	1.00	2	2.1	1.00	1	1.1	1.00						
SOMNOLENCE	Reboxetine	2	1.8	1.00	3	2.8	1.00	2	2.0	1.00	2	2.0	1.50	3	3.2	1.33	1	1.1	1.00						
	Imipramine	6	5.2	1.00	5	4.7	1.00	4	4.2	1.00	4	4.5	1.00	3	3.5	1.00	2	2.5	1.00	1	5.9	1.00			
	Placebo	3	2.7	1.00	4	3.7	1.00	2	2.0	1.00	5	5.2	1.00	5	5.6	1.00	4	4.6	1.00	3	13.0	1.00			
AGITATION	Reboxetine						1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00	1	1.1	1.00				
	Imipramine	3	2.6	1.00	3	2.8	1.00	3	3.1	1.00	2	2.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00			
	Placebo	4	3.6	1.00	5	4.7	1.00	2	2.0	1.00	2	2.1	1.00	2	2.1	1.00	1	1.1	1.00						
FATIGUE	Reboxetine	2	1.8	1.00	4	3.8	1.00	5	4.9	1.00	3	3.1	1.00	1	1.1	1.00	1	1.1	1.00	2	2.2	1.00			
	Imipramine						1	1.0	1.00	2	2.1	1.00	2	2.2	1.00	4	4.7	1.00	4	4.9	1.00	3	17.6	1.00	
	Placebo				3	2.8	1.00	4	3.9	1.00	2	2.1	1.00	2	2.2	1.00	1	1.1	1.00	1	1.1	1.00	4	4.3	1.00
VERTIGO	Reboxetine	1	0.9	1.00	1	0.9	1.00	2	2.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00	1	1.1	1.00	4	7.1	1.00
	Imipramine	5	4.3	1.00	2	1.9	1.00	2	2.1	1.00	3	3.4	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00			

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment																								
		0-7			8-14			15-21			22-28			29-35			36-42			> 42						
		No Pt.	X on exp. (*)	No Pt. exp. (*)	No Pt.	X on exp. (*)	No Pt. exp. (*)	No Pt.	X on exp. (*)	No Pt. exp. (*)	No Pt.	X on exp. (*)	No Pt. exp. (*)	No Pt.	X on exp. (*)	No Pt. exp. (*)	No Pt.	X on exp. (*)	No Pt. exp. (*)	No Pt.	X on exp. (*)	No Pt. exp. (*)				
VERTIGO	Reboxetine	3	2.7	1.00	4	3.8	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00	1	1.1	1.00	1	7.1	1.00	
	Imipramine	2	1.7	1.00	3	2.8	1.00	4	4.2	1.00	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00				
	Placebo	1	0.9	1.00	3	2.8	1.00	2	2.0	1.00	1	1.0	1.00													
MICTURITION DISORDER	Reboxetine							1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00							
	Imipramine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	5.9	1.00	
	Placebo	1	0.9	1.00	1	0.9	1.00																			
HOT FLUSHES	Reboxetine	1	0.9	1.00	1	0.9	1.00	2	2.0	1.00	3	3.1	1.00	3	3.2	1.00	3	3.2	1.00	3	3.3	1.00				
	Imipramine	1	0.9	1.00	2	1.9	1.00	3	3.1	1.00	2	2.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	5.9	1.00	
	Placebo													1	1.1	1.00	1	1.1	1.00	1	1.1	1.00				
PARAESTHESIA	Reboxetine				1	0.9	1.00	2	2.0	1.00	2	2.0	1.00	2	2.0	1.00	2	2.4	1.00	2	2.4	1.00	1	1.1	1.00	
	Imipramine	4	3.5	1.00	4	3.7	1.00	2	2.1	1.00	2	2.2	1.00	2	2.2	1.00	2	2.4	1.00	2	2.4	1.00	1	1.1	1.00	
	Placebo	1	0.9	1.00				1	1.0	1.00																
RHINITIS	Reboxetine	2	1.8	1.00																						
	Imipramine	1	0.9	1.00	1	0.9	1.00	2	2.1	1.00	2	2.1	1.00	2	2.2	1.00	2	2.4	1.00	2	2.4	1.00	1	1.2	1.00	
	Placebo	1	0.9	1.00	1	0.9	1.00	2	2.0	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00				
HYPOTENSION POSTURAL	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00																
	Imipramine	4	3.5	1.00	3	2.8	1.00				1	1.1	1.00	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	5.9	1.00	
	Placebo	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00	1	1.1	1.00				
HEIGHT INCREASE	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	1	1.0	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	
	Imipramine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	2	2.2	1.00	2	2.4	1.00	2	2.4	1.00	2	2.5	1.00	
	Placebo	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	1	1.0	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	

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(*) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment																					
		0-7		8-14		15-21		22-28		29-35		36-42		> 42									
		No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)								
APPETITE INCREASED	Imipramine	2	1.7	1.00	2	1.9	1.00	2	2.1	1.00	2	2.2	1.00	2	2.4	1.00	2	2.5	1.00	2	11.8	1.00	
	Placebo	1	0.9	1.00	1	0.9	1.00																
DYSPEPSIA	Imipramine	1	0.9	1.00	1	0.9	1.00	3	3.1	1.00	2	2.2	1.00	2	2.4	1.00	3	3.7	1.00	2	11.8	1.00	
	Placebo	1	0.9	1.00	1	0.9	1.00																
URINARY RETENTION	Placebo	1	0.9	1.00																			
	Reboxetine	3	2.7	1.00	3	2.8	1.00	2	2.0	1.00	2	2.0	1.00	2	2.2	1.00	1	1.1	1.00				
NERVOUSNESS	Placebo				1	0.9	1.00	1	1.0	1.00													
	Reboxetine	2	1.8	1.00	4	3.8	1.00	2	2.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00	1	7.1	1.00	
ASTHENIA	Imipramine	2	1.7	1.00	2	1.9	1.00	2	2.1	1.00	2	2.2	1.00	2	2.4	1.00	1	1.2	1.00	1	5.9	1.00	
	Reboxetine	1	0.9	1.00																			
TACHYCARDIA	Imipramine	2	1.7	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00	1	1.2	1.00							
	Reboxetine	2	1.8	1.00	1	0.9	1.00	2	2.0	1.00	1	1.0	1.00										
URINARY TRACT INFECTION	Placebo																						
	Reboxetine				3	2.9	1.00	3	3.1	1.00	3	3.1	1.00	2	2.2	1.00	1	1.1	1.00	1	7.1	1.00	
PALPITATION	Imipramine	1	0.9	1.00	1	0.9	1.00	2	2.1	1.00	2	2.2	1.00	1	1.2	1.00	1	1.2	1.00	1	5.9	1.00	
	Placebo							1	1.0	1.00													
SUICIDE ATTEMPT	Reboxetine	1	0.9	1.00																			
	Imipramine	2	1.7	1.00											1	1.2	1.00	1	1.2	1.00	1	5.9	1.00
	Placebo							1	1.0	1.00	2	2.1	1.00	2	2.2	1.00							
	Reboxetine	1	0.9	1.00																			

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 50

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment														
		0-7		8-14		15-21		22-28		29-35		36-42		> 42		
		No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	
HYPOTENSION	Imipramine			1	0.9	1.00										
	Placebo	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00
DYSPNOEA	Reboxetine	1	0.9	1.00	1	0.9	1.00									
	Imipramine	2	1.7	1.00	1	0.9	1.00									
FLATULENCE	Reboxetine							2	2.0	1.00	2	2.2	1.00	2	2.2	1.00
	Placebo							1	0.9	1.00	1	1.0	1.00	1	1.1	1.00
HYPERKINESIA	Reboxetine							1	0.9	1.00	1	1.0	1.00			
	Imipramine	1	0.9	1.00	1	0.9	1.00									
HYPERTENSION	Placebo	1	0.9	1.00	2	1.9	1.00	1	1.0	1.00	1	1.0	1.00			
	Imipramine	1	0.9	1.00												
VOMITING	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00
	Imipramine	1	0.9	1.00												
SLEEP DISORDER	Placebo	2	1.8	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00			
	Reboxetine	1	0.9	1.00												
HEIGHT DECREASE	Imipramine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	1	1.2	1.00
	Placebo							1	1.0	1.00	1	1.0	1.00	1	1.1	1.00
SINUSITIS	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00			
	Placebo							1	0.9	1.00	1	1.0	1.00	1	1.1	1.00
	Reboxetine							1	0.9	1.00	1	1.0	1.00			
	Placebo															

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment																	
		0-7		8-14		15-21		22-28		29-35		36-42		> 42					
		No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)				
MUSCLE CONTRACTIONS INVOLUNTARY	Imipramine	1	1.0	2	2.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	5.9	1.00	
RASH	Imipramine	1	1.0	1.00						1	1.2	1.00	1	1.2	1.00	2	8.7	1.00	
	Placebo												2	2.3	1.00	2	8.7	1.00	
ANXIETY	Imipramine						1	1.1	1.00										
	Placebo	3	2.7	1.00	1	0.9	1.00												
	Reboxetine	1	0.9	1.00															
PERINEAL PAIN MALE	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00
	Imipramine	1	0.9	1.00	1	0.9	1.00												
	Placebo	2	1.8	1.00	1	0.9	1.00												
	Imipramine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00						
	Reboxetine	1	0.9	1.00															
CONJUNCTIVITIS	Imipramine	1	0.9	1.00	2	1.9	1.00	1	1.0	1.00	1	1.1	1.00						
	Placebo	1	0.9	1.00	2	1.9	1.00	1	1.0	1.00	1	1.1	1.00						
	Placebo	3	2.7	1.00	2	1.9	1.00												
	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00			
EPIDIDYMITIS	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00			
	Placebo							1	1.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00
	Placebo																		

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(*) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment																	
		0-7		8-14		15-21		22-28		29-35		36-42		> 42					
		No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)	No Pt.	% exp. (*)				
TINNITUS	Imipramine	1	0.9	1.00	2	1.9	1.00	1	1.0	1.00									
TASTE LOSS	Imipramine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00						
DYSURIA	Imipramine	1	0.9	1.00															
	Reboxetine	2	1.8	1.00	1	0.9	1.00												
ARTHRALGIA	Placebo	1	0.9	1.00	1	0.9	1.00												
	Reboxetine													1	1.1	1.00	1	1.1	1.00
ANOREXIA	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00						
HYDRIASIS	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00						
RHAGADES	Imipramine							1	1.0	1.00	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00
CONCENTRATION IMPAIRED	Imipramine										1	1.1	1.00	1	1.2	1.00	1	1.2	1.00
INFLUENZA-LIKE SYMPTOMS	Imipramine										1	1.1	1.00	1	1.2	1.00			
	Placebo										1	1.0	1.00						
	Reboxetine													1	1.1	1.00			
HYPERURICAEMIA	Reboxetine													1	1.0	1.00	1	1.1	1.00
DYSPHAGIA	Imipramine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00									
SALIVA INCREASED	Reboxetine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00									
DUODENAL ULCER REACTIVATED	Imipramine										1	0.9	1.00	1	1.0	1.00	1	1.1	1.00

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment														
		0-7		8-14		15-21		22-28		29-35		36-42		> 42		
		No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	
GANMA-GT INCREASED	Imipramine															
	Reboxetine			1	1.0	1.00	1	1.0	1.00					1	1.2	1.00
SPEECH DISORDER	Imipramine															
	Reboxetine															
HYPERTONIA	Placebo															
	Imipramine															
	Reboxetine															
DEPERSONALIZATION	Imipramine	1	0.9	1.00	1	0.9	1.00									
	Reboxetine															
SYNCOPE	Imipramine	1	0.9	1.00	1	0.9	1.00									
	Reboxetine															
CHEST PAIN	Imipramine	1	0.9	1.00												
	Reboxetine	1	0.9	1.00												
MICTURITION FREQUENCY	Placebo	1	0.9	1.00	1	0.9	1.00									
	Imipramine															
	Reboxetine															
EYE ABNORMALITY	Reboxetine	1	0.9	1.00	1	0.9	1.00									
	Imipramine															
	Reboxetine															
TOOTH DISORDER	Reboxetine	1	0.9	1.00	1	0.9	1.00									
	Imipramine															
COLD	Imipramine															
	Reboxetine															
RIGORS	Imipramine	1	0.9	1.00	1	0.9	1.00									
	Reboxetine															
PHARYNGITIS	Placebo	1	0.9	1.00	1	0.9	1.00									
	Imipramine															
	Reboxetine															
FLUSHING	Reboxetine	1	0.9	1.00	1	0.9	1.00									
	Imipramine															
HAEMORRHOIDS THROMBOSED	Reboxetine	1	0.9	1.00	1	0.9	1.00									
	Imipramine															

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment														
		0-7		8-14		15-21		22-28		29-35		36-42		> 42		
		No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	
TONGUE ULCERATION	Placebo															
LIBIDO DECREASED	Reboxetine															
TASTE PERVERSION	Placebo															
PARONYCHIA	Placebo															
ACCOMMODATION ABNORMAL	Imipramine															
AUTOLESIONIST BEHAVIOUR	Imipramine	1	0.9	1.00												
MIGRAINE	Reboxetine	1	0.9	1.00												
HYPERPYREXIA	Reboxetine	1	0.9	1.00												
COLITIS	Imipramine															
EXTRASYSTOLES	Imipramine															
BRADYCARDIA	Placebo															
CHROMATOPSIA	Placebo															
MALaise	Placebo															
HYPOKALAEMIA	Imipramine															
DEPRESSION AGGRAVATED	Placebo															
GASTRITIS	Reboxetine															
PYURIA	Reboxetine															

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 60

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Assigned treatment	Days of treatment															
		0-7		8-14		15-21		22-28		29-35		36-42		> 42			
		No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)	No Pt.	% on exp. (*)		
GASTROENTERI-TIS	Reboxetine									1	1.1						
PHOSPHATASE ALKALINE INCREASED	Imipramine													1	1.2	1.00	
ANEMIA HYPOCHROMIC	Imipramine													1	1.2	1.00	
EOSINOPHILIA	Imipramine													1	1.2	1.00	
BRONCHITIS	Placebo													1	1.1	1.00	
HERPES SIMPLEX	Placebo													1	1.1	1.00	
RASH ERYTHEMATOUS	Reboxetine													1	1.1	1.00	
HYPERTRIGLYCERIDAEMIA	Imipramine													1	1.1	1.00	
														1	5.9	1.00	

(*) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: AUTONOMIC NERVOUS SYSTEM DISORDERS

Adverse events/Assigned treatment	Days of treatment																				
	0-7		8-14		15-21		22-28		29-35		36-42		> 42								
	No Pt	Z on exp. (%)	No Pt	Z on exp. (%)	No Pt	Z on exp. (%)	No Pt	Z on exp. (%)	No Pt	Z on exp. (%)	No Pt	Z on exp. (%)	No Pt	Z on exp. (%)							
MOUTH DRY	33	28.7	1.00	37	34.6	1.00	33	34.4	1.00	32	36.0	1.00	27	31.8	1.00	26	32.1	1.00	14	32.4	1.00
	8	7.1	1.00	7	6.5	1.00	9	8.8	1.00	10	10.3	1.00	8	9.0	1.00	5	5.7	1.00	3	13.0	1.00
	17	15.2	1.00	22	20.8	1.04	22	21.6	1.04	19	19.4	1.05	16	17.2	1.00	14	15.6	1.00	8	57.1	1.00
SWEATING INCREASED	15	13.0	1.00	17	15.9	1.00	9	9.4	1.00	11	12.4	1.00	9	10.6	1.00	9	11.1	1.00	4	23.5	1.25
	2	1.8	1.00	2	1.9	1.00	2	2.0	1.00	2	2.1	1.00	2	2.2	1.00	2	2.3	1.00	2	8.7	1.00
	7	6.3	1.00	11	10.4	1.00	9	8.8	1.11	9	9.2	1.00	5	5.4	1.00	4	4.4	1.00	1	7.1	1.00
SALIVA INCREASED	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00												

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: BODY AS A WHOLE-GENERAL DISORDERS

Adverse events/Assigned treatment	Days of treatment																					
	0-7		8-14		15-21		22-28		29-35		36-42		> 42									
	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)								
ASTHENIA / FATIGUE	2	1.7	1.00	2	1.9	1.00	2	2.1	1.50	3	3.4	1.33	5	5.9	1.20	4	4.9	1.25	3	17.6	1.33	
				3	2.8	1.00	4	3.9	1.00	2	2.1	1.00	2	2.2	1.00	1	1.1	1.00	1	4.3	1.00	
	2	1.8	1.00	1	0.9	1.00	2	2.0	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00	1	7.1	1.00	
INFLUENZA-LIKE SYMPTOMS							1	1.1	1.00	1	1.1	1.00	1	1.2	1.00							
							1	1.0	1.00													
CHEST PAIN	1	0.9	1.00																			
	1	0.9	1.00																			
RIGORS																						
				1	0.9	1.00	1	1.0	1.00													
	1	0.9	1.00																			
HYPERPYREXIA																						
MALAISE																						

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: CARDIOVASCULAR DISORDERS, GENERAL

Adverse events/Assigned treatment	Days of treatment														
	0-7		8-14		15-21		22-28		29-35		36-42		> 42		
	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	
HYPOTENSION AND RELATED SYMPTOMS	Imipramine	9	7.8	14	13.1	7	7.3	7	7.9	4	4.7	4	4.9	3	17.6
	Placebo	2	1.8	2	1.9	4	3.9	3	3.1	2	2.2				
	Reboxetine	4	3.6	5	4.7	3	2.9	5	5.1	5	5.4	1	1.1		
FLUSHING / HOT FLUSHES	Imipramine	1	0.9	2	1.9	3	3.1	2	2.2	1	1.2	1	1.2	1	5.9
	Placebo											1	1.1	1	1.0
	Reboxetine														
TACHYCARDIA	Imipramine	2	1.7	1	0.9	1	1.0	1	1.1	1	1.2				
	Reboxetine	2	1.8	1	0.9	2	2.0	1	1.0						
	Imipramine	1	0.9	1	0.9	2	2.1	2	2.2	1	1.2	1	1.2	1	5.9
PALPITATION	Placebo					1	1.0								
	Reboxetine	1	0.9												
	Imipramine	1	0.9												
HYPERTENSION	Imipramine	1	0.9												
	Reboxetine	1	0.9												
	Placebo														
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Imipramine	1	0.9	2	1.9	1	1.0								
	Placebo														
	Reboxetine														
HAEMORRHOIDS THROBSED	Imipramine	1	0.9	1	0.9	1	1.0								
	Placebo														
	Reboxetine														
EXTRASYSTOLES	Imipramine					1	1.0								
	Placebo														
	Reboxetine														

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO

Adverse events/Assigned treatment	Days of treatment														
	0-7		8-14		15-21		22-28		29-35		36-42		> 42		
	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	
TREMOR	Imipramine	6	5.2	12	11.2	16	16.7	13	14.6	11	12.9	8	9.9	4	23.5
	Placebo	4	3.6	3	2.8	1.00				1	1.1	1.00			
	Reboxetine	4	3.6	3	2.8	1.00	3	2.9	1.00	1	1.0	1.00			
HEADACHE / MIGRAINE	Imipramine	4	3.5	5	4.7	3	3.1	4	4.5	2	2.4	1.00	2	2.5	1.00
	Placebo	3	2.7	4	3.7	1.00	5	4.9	1.00	4	4.5	1.00	3	3.4	1.00
	Reboxetine	11	9.8	8	7.5	1.12	5	4.9	1.00	6	6.1	1.00	3	3.3	1.00
VERTIGO	Imipramine	5	4.3	2	1.9	2	2.1	3	3.4	1	1.2	1.00	1	1.2	1.00
	Placebo	3	2.7	4	3.8	1.00	1	1.0	1.00	1	1.0	1.00	1	1.1	1.00
	Reboxetine	4	3.5	4	3.7	1.00	2	2.1	1.00	2	2.4	1.00	1	1.2	1.00
PARAESTHESIA	Imipramine	1	0.9	1.00											
	Placebo	2	1.8	1.00											
	Reboxetine	1	0.9	1.00	1	0.9	1.00								
HYPERKINESIA	Imipramine	1	0.9	1.00	2	1.9	1.00	1	1.0	1.00					
	Placebo	1	0.9	1.00	2	1.9	1.00	1	1.0	1.00					
	Reboxetine														
MUSCLE CONTRACTIONS INVOLUNTARY	Imipramine						1	1.0	1.00	2	2.2	1.00	1	1.2	1.00
	Placebo						1	1.0	1.00						
	Reboxetine						1	1.0	1.00						
CONFUSION	Imipramine	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00					
	Placebo														
	Reboxetine	1	0.9	1.00											
SPEECH DISORDER	Imipramine														
	Placebo														
	Reboxetine														
HYPERTONIA	Imipramine														
	Placebo														
	Reboxetine														

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/015

TABLE No. : 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: GASTRO-INTESTINAL SYSTEM DISORDERS

Adverse events/Assigned treatment	Days of treatment														
	0-7		8-14		15-21		22-28		29-35		36-42		> 42		
	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	
CONSTIPATION	Imipramine	5	4.3	12	11.2	14	14.6	12	13.5	12	14.1	12	14.8	9	52.9
	Placebo	1	0.9	4	3.7	3	2.9	3	3.1	4	4.5	4	4.6	2	8.7
	Reboxetine	7	6.3	14	13.2	13	12.7	12	12.2	10	10.8	9	10.0	4	28.6
NAUSEA AND RELATED SYMPTOMS	Imipramine	8	7.0	8	7.5	9	9.4	7	7.9	3	3.5	6	7.4	4	23.5
	Placebo	4	3.6	5	4.7	3	2.9	4	4.1	3	3.4	1	1.1		
	Reboxetine	6	5.4	3	2.8	5	4.9	5	5.1	3	3.2	2	2.2	1	7.1
ABDOMINAL PAIN	Imipramine	2	1.7	3	2.8	4	4.2	1	1.1	1	1.2	1	1.2		
	Placebo	1	0.9	3	2.8	2	2.0	1	1.0						
	Reboxetine					1	1.0	1	1.0	1	1.1				
APPETITE INCREASED	Imipramine	2	1.7	2	1.9	2	2.1	2	2.2	2	2.4	2	2.5	2	11.8
	Placebo	1	0.9	1	0.9	1	1.0								
	Reboxetine														
FLATULENCE	Imipramine			1	0.9	1	1.0	1	1.0	1	1.1	1	1.1	1	4.3
	Placebo														
	Reboxetine														
DIARRHOEA	Imipramine	3	2.7	2	1.9	2	2.0								
	Placebo	1	0.9	1	0.9	1	1.0	1	1.0	1	1.1	1	1.1		
	Reboxetine														
ANOREXIA	Imipramine	1	0.9	1	0.9	1	1.0	1	1.0	1	1.0	1	1.0		
	Placebo														
	Reboxetine														
DYSPHAGIA	Imipramine														
	Placebo														
	Reboxetine														
DUODENAL ULCER REACTIVATED	Imipramine														
	Placebo														
	Reboxetine														
TOOTH DISORDER	Imipramine														
	Placebo														
	Reboxetine	1	0.9	1	0.9	1	1.0								

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(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

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PHARNACIA CNS R&D

REBOXETINE - PROTOCOLI. 2012/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: GASTRO-INTESTINAL SYSTEM DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)
TONGUE ULCERATION					1	1.0	1	1.0	1.00					
COLITIS					1	1.0	1.00							
GASTROENTERI- TIS									1	1.1	1.00			

(*) number of adverse events on number of patient who complained of adverse events
(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No. : 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: HEARING AND VESTIBULAR DISORDERS

Adverse events/Assigned treatment	Days of treatment																		
	0-7		8-14		15-21		22-28		29-35		36-42		> 42						
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)					
TINNITUS	1	0.9	1.00	2	1.9	1.00	1	1.0	1.00										
Inipramine																			

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: HEMATOLOGY DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)
ANEMIA														
EOSINOPHILIA														
Inipramine												1	1.2	1.00
Inipramine												1	1.2	1.00

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: LIVER AND BILIAR SYSTEM DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)
INCREASED LIVER ENZYMES														
Imipramine														
Reboxetine			1	1.0	1.00	1	1.0	1.00						

(*) number of adverse events on number of patient who complained of adverse events
 (some adverse events are grouped in cluster)

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: METABOLIC AND NUTRITIONAL DISORDERS

Adverse events/Assigned treatment	Days of treatment																	
	0-7		8-14		15-21		22-28		29-35		36-42		> 42					
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)				
WEIGHT INCREASE	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	2	2.4	1.00	2	2.5	1.00	1	5.9	1.00
	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00	1	7.1	1.00
WEIGHT DECREASE							1	1.0	1.00	1	1.1	1.00						
	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00						
HYPERURICAEMIA																		
							1	1.0	1.00	1	1.1	1.00	1	1.1	1.00	1	7.1	1.00
HYPOKALAEMIA																		
							1	1.1	1.00									
PHOSPHATASE ALKALINE INCREASED																		
													1	1.2	1.00			
HYPERTRIGLYCERIDAEMIA																		
																1	5.9	1.00

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: MUSCULO-SKELETAL SYSTEM DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)
MYALGIA	1	0.9	1.00	1	0.9	1.00								
	2	1.8	1.00	1	0.9	1.00								
BACK PAIN							1	1.0	1.00	1	1.1	1.00	1	1.1
ARTHRALGIA	1	0.9	1.00	1	0.9	1.00								
Reboxetine										1	1.1	1.00	1	1.1

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 51

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: PSYCHIATRIC DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)
INSOMNIA	Imipramine	4 3.5 1.00	5 4.7 1.00	4 4.2 1.00	3 3.4 1.00	4 4.7 1.00	3 3.7 1.00	2 2.3 1.00	5 5.6 1.00	1 1.2 1.00	2 11.8 1.00	1 4.3 1.00		
	Placebo	2 1.8 1.00	2 1.9 1.00	1 1.0 1.00	2 2.1 1.00	2 2.2 1.00	2 2.3 1.00	2 2.3 1.00	2 2.3 1.00	2 2.3 1.00	2 11.8 1.00	1 4.3 1.00		
	Reboxetine	6 5.4 1.00	5 4.7 1.00	6 5.9 1.00	4 4.1 1.00	4 4.3 1.00	4 4.3 1.00	5 5.6 1.00	1 1.2 1.00					
AGITATION / ANXIETY / NERVOUSNESS	Imipramine	3 2.6 1.00	3 2.8 1.00	3 3.1 1.00	3 3.4 1.00	3 3.4 1.00	1 1.2 1.00							
	Placebo	7 6.3 1.00	7 6.5 1.00	3 2.9 1.00	2 2.1 1.00	1 1.1 1.00								
	Reboxetine	5 4.5 1.00	7 6.6 1.14	7 6.9 1.00	4 4.1 1.00	2 2.2 1.00	3 3.3 1.00	3 3.3 1.00	2 2.5 1.00	1 1.1 1.00	2 14.3 1.00			
SOMNOLENCE	Imipramine	6 5.2 1.00	5 4.7 1.00	4 4.2 1.00	4 4.5 1.00	3 3.5 1.00	2 2.5 1.00	4 4.6 1.00	3 13.0 1.00	1 7.1 1.00				
	Placebo	3 2.7 1.00	4 3.7 1.00	2 2.0 1.00	5 5.2 1.00	5 5.6 1.00	4 4.6 1.00	1 1.1 1.00	1 1.2 1.00	1 5.9 1.00				
	Reboxetine			1 1.0 1.00	1 1.0 1.00	1 1.0 1.00	1 1.2 1.00	2 2.2 1.00						
SUICIDE ATTEMPT	Imipramine	2 1.7 1.00												
	Placebo			1 1.0 1.00	2 2.1 1.00	2 2.2 1.00								
	Reboxetine	1 0.9 1.00	1 0.9 1.00	1 1.0 1.00	1 1.1 1.00	1 1.2 1.00	1 1.2 1.00	1 1.2 1.00	1 1.2 1.00	1 5.9 1.00				
SLEEP DISORDER	Imipramine													
	Placebo													
	Reboxetine	1 0.9 1.00	1 0.9 1.00	1 1.0 1.00	1 1.1 1.00	1 1.2 1.00	1 1.2 1.00	1 1.2 1.00	1 1.2 1.00	1 5.9 1.00				
CONCENTRATION IMPAIRED	Imipramine													
	Placebo													
	Reboxetine													
DEPERSONALIZATION	Imipramine													
	Placebo													
	Reboxetine													
LIBIDO DECREASED	Imipramine													
	Placebo													
	Reboxetine													
PAROXISMA	Imipramine													
	Placebo													
	Reboxetine													
AUTOLESTIONIST BEHAVIOUR	Imipramine													
	Placebo													
	Reboxetine													

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

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PRAXACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: PSYCHIATRIC DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)
DEPRESSION AGGRAVATED							1	1.0	1.00					

(*) number of adverse events on number of patient who complained of adverse events
(some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CMS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: REPRODUCTIVE DISORDERS, MALE

Adverse events/Assigned treatment	Days of treatment																
	0-7		8-14		15-21		22-28		29-35		36-42		> 42				
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)			
PERINEAL PAIN MALE	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00		
EPIDIDYMITIS	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00		
IMPOTENCE	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00	1	1.1	1.00		

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R8D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: RESISTANCE MECHANISM DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)
HERPES SIMPLEX														
Placebo											1	1.1	1.00	

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: RESPIRATORY SYSTEM DISORDERS

Adverse events/Assigned treatment	Days of treatment																	
	0-7		8-14		15-21		22-28		29-35		36-42		> 42					
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)				
RHINITIS	1	0.9	1.00	1	0.9	1.00	2	2.1	1.00	2	2.2	1.00	2	2.4	1.00	1	1.2	1.00
	1	0.9	1.00	1	0.9	1.00	2	2.0	1.00	1	1.0	1.00	1	1.1	1.00			
	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00									
DYSPNOEA	2	1.7	1.00	1	0.9	1.00												
SINUSITIS													2	2.0	1.00	2	2.2	1.00
													1	1.0	1.00	1	1.1	1.00
PHARYNGITIS																		
													1	0.9	1.00	1	1.0	1.00
BRONCHITIS																		
													1	0.9	1.00	1	1.1	1.00

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: SKIN AND APPENDAGES DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)
ERYTHEMA / RASH	Imipramine								1 1.2		1 1.2		1 5.9	
	Placebo										2 2.3		2 8.7	
	Reboxetine										1 1.1			
RHAGADES	Imipramine		1 1.0		1 1.1		1 1.1		1 1.2		1 1.2			
COLD	Imipramine		1 0.9		1 1.0									
URTICARIA	Imipramine		1 0.9		1 1.0									

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R8D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: SPECIAL SENSES OTHER, DISORDERS

Adverse events/Assigned treatment	Days of treatment																	
	0-7		8-14		15-21		22-28		29-35		36-42		> 42					
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)				
TASTE LOSS	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00						
TASTE PERVERSION							1	1.0	1.00	1	1.1	1.00						

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/045

TABLE No. : 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: URINARY SYSTEM DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)	No Pt	Z on exp. (*)
URINARY HESITANCY / RETENTION	1	0.9 1.00	1	0.9 1.00	1	1.0 1.00	1	1.1 1.00	1	1.2 1.00	1	1.2 1.00	1	5.9 1.00
	2	1.8 1.00	1	0.9 1.00										
	4	3.6 1.00	4	3.8 1.00	4	3.9 1.00	5	5.1 1.00	5	5.4 1.00	4	4.4 1.00		
URINARY TRACT INFECTION														
					3	2.9 1.00	3	3.1 1.00	2	2.2 1.00	1	1.1 1.00	1	7.1 1.00
DYSURIA	1	0.9 1.00												
	2	1.8 1.00	1	0.9 1.00										
MICTURITION FREQUENCY	1	0.9 1.00	1	0.9 1.00										
PYURIA								1	1.0 1.00					

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 61

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: VISION DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)	No Pt	% on exp. (*)
BLURRED VISION	3	2.6	6	5.6	5	5.2	5	5.6	7	8.2	6	7.4	4	23.5
			3	2.8	3	2.9	3	3.1	3	3.4	3	3.4	2	8.7
			3	2.7	3	2.8	3	2.9	3	3.1	3	3.2	1	1.1
CONJUNCTIVITIS	1	0.9	2	1.9	1	1.0	1	1.1						
			1	0.9	1	1.0	1	1.0						
			1	0.9	1	1.0	1	1.0						
EYE ABNORMALITY	1	0.9	1	0.9										
			1	0.9										
			1	0.9										
CHROMATOPSIA					1	1.0								
					1	1.0								
					1	1.0								

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 62

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND GROUPED BY BODY SYSTEM

Body system Pt exposed	Assigned treatment	Days of treatment																				
		0-7			8-14			15-21			22-28			29-35			36-42			> 42		
		No Pt	% on exp	(*)	No Pt	% on exp	(*)	No Pt	% on exp	(*)	No Pt	% on exp	(*)	No Pt	% on exp	(*)	No Pt	% on exp	(*)	No Pt	% on exp	(*)
AUTONOMIC NERVOUS SYSTEM DISORDERS	Imipramine	115	400	2.33	107	400	2.70	96	100	2.73	89	100	2.45	85	100	2.46	81	100	2.46	17	100	2.42
	Placebo	112	300	1.62	107	300	1.68	102	300	1.67	97	300	1.75	89	300	1.92	87	300	1.78	23	300	1.81
	Reboxetine	112	300	2.10	106	300	2.24	102	300	2.22	98	300	2.19	93	300	1.97	90	300	1.84	14	300	1.47
GASTRO-INTESTINAL SYSTEM DISORDERS	Imipramine	38	33.0	1.26	44	41.1	1.22	37	38.5	1.13	37	41.6	1.16	31	36.5	1.16	29	35.8	1.20	16	94.1	1.18
	Placebo	10	8.9	1.00	9	8.4	1.00	11	10.8	1.00	11	10.8	1.00	12	12.4	1.00	10	11.2	1.00	7	8.0	1.00
	Reboxetine	24	21.4	1.04	33	31.1	1.06	31	30.4	1.09	27	27.6	1.07	20	21.5	1.05	17	18.9	1.05	9	64.3	1.00
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Imipramine	17	14.8	1.05	24	22.4	1.16	26	27.1	1.26	20	22.5	1.15	18	21.2	1.00	19	23.5	1.10	14	82.4	1.07
	Placebo	8	7.1	1.50	12	11.2	1.41	7	6.9	1.57	8	8.2	1.37	6	6.7	1.33	5	5.7	1.20	2	8.7	1.50
	Reboxetine	14	12.5	1.14	19	17.9	1.05	18	17.6	1.16	18	18.4	1.11	14	15.1	1.07	11	12.2	1.00	5	35.7	1.00
PSYCHIATRIC DISORDERS	Imipramine	19	16.5	1.10	20	18.7	1.25	20	20.8	1.25	22	24.7	1.18	16	18.8	1.12	13	16.0	1.07	6	35.3	1.00
	Placebo	8	7.1	1.12	9	8.4	1.00	7	6.9	1.00	6	6.2	1.00	6	6.7	1.00	4	4.6	1.00	1	4.3	1.00
	Reboxetine	21	18.8	1.00	15	14.2	1.06	9	8.8	1.11	8	8.2	1.00	6	6.5	1.00	4	4.4	1.00	3	21.4	1.00
CARDIOVASCULAR DISORDERS, GENERAL	Imipramine	16	13.9	1.12	14	13.1	1.07	12	12.5	1.00	12	13.5	1.00	11	12.9	1.00	9	11.1	1.00	6	35.3	1.00
	Placebo	11	9.8	1.09	12	11.2	1.08	7	6.9	1.00	11	11.3	1.18	9	10.1	1.22	6	6.9	1.00	4	17.4	1.00
	Reboxetine	10	8.9	1.20	10	9.4	1.30	12	11.8	1.25	10	10.2	1.00	7	7.5	1.00	9	10.0	1.00	4	28.6	1.00
VISION DISORDERS	Imipramine	14	12.2	1.21	18	16.8	1.11	14	14.6	1.07	11	12.4	1.09	7	8.2	1.00	6	7.4	1.00	5	29.4	1.00
	Placebo	2	1.8	1.00	3	2.8	1.00	6	5.9	1.00	3	3.1	1.00	3	3.4	1.00	1	1.1	1.00			
	Reboxetine	7	6.3	1.14	9	8.5	1.11	9	8.8	1.11	9	9.2	1.11	7	7.5	1.14	3	3.3	1.00			
Imipramine	4	3.5	1.00	8	7.5	1.00	6	6.3	1.00	6	6.7	1.00	7	8.2	1.00	6	7.4	1.00	4	23.5	1.00	

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(*) number of adverse events on number of patient who complained of adverse events

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 62

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND GROUPED BY BODY SYSTEM

Body system	Assigned treatment	Days of treatment													
		0-7		8-14		15-21		22-28		29-35		36-42		> 42	
		No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)
VISION DISORDERS	Reboxetine	5	4.5	3	2.8	4	3.9	3	3.1	3	3.4	3	3.4	2	8.7
	Placebo														
BODY AS A WHOLE-GENERAL DISORDERS	Reboxetine	3	2.6	3	2.8	3	3.1	4	4.5	6	7.1	4	4.9	3	17.6
	Imipramine														
	Placebo	3	2.8	3	2.8	5	4.9	3	3.1	2	2.2	1	1.1	1	4.3
URINARY SYSTEM DISORDERS	Reboxetine	4	3.6	1	0.9	2	2.0	1	1.0	1	1.0	2	2.2	1	7.1
	Imipramine	2	1.7	1	0.9	1	1.0	1	1.1	1	1.2	1	1.2	1	5.9
	Placebo	3	2.7	2	1.9	2	1.9					1	1.1	1	4.3
RESPIRATORY SYSTEM DISORDERS	Reboxetine	6	5.4	5	4.7	7	6.9	9	9.2	7	7.5	5	5.6	1	7.1
	Imipramine	3	2.6	2	1.9	2	2.1	2	2.2	2	2.4	1	1.2		
	Placebo	1	0.9	3	2.8	4	3.9	2	2.1	2	2.2	1	1.1		
METABOLIC AND NUTRITIONAL DISORDERS	Reboxetine	1	0.9	2	1.9	1	1.0	2	2.0	2	2.2	2	2.2	2	11.8
	Imipramine	1	0.9	1	0.9	1	1.0	3	3.4	2	2.4	3	3.7	2	11.8
	Placebo					1	1.0	1	1.0	1	1.1				
REPRODUCTIVE DISORDERS, MALE	Reboxetine	1	0.9	1	0.9	1	1.0	2	2.0	2	2.2	2	2.2	2	14.3
	Imipramine	2	1.8	2	1.9	2	2.0	2	2.0	2	2.2	1	1.1		
	Placebo	3	2.7	2	1.9	1	1.0	1	1.0	1	1.1	1	1.1	1	4.3
MUSCULO-SKELETAL DISORDERS	Reboxetine														
	Imipramine	1	0.9	1	0.9										
	Placebo	3	2.7	2	1.9	1	1.0	1	1.0	1	1.1	1	1.1	1	4.3
	Reboxetine														

(CONTINUED)

(*) number of adverse events on number of patient who complained of adverse events

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 62

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND GROUPED BY BODY SYSTEM

Body system	Assigned treatment	Days of treatment																	
		0-7		8-14		15-21		22-28		29-35		36-42		> 42					
		No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)	No Pt	% on exp (*)				
SKIN AND APPENDAGES DISORDERS	Imipramine	1	0.9	1.00	2	2.1	1.00	1	1.1	1.00	2	2.4	1.00	2	2.5	1.00	1	5.9	1.00
	Placebo													2	2.3	1.00	2	8.7	1.00
	Reboxetine													1	1.1	1.00			
	Imipramine	1	0.9	1.00	1	0.9	1.00	1	1.1	1.00	1	1.1	1.00						
SPECIAL SENSES OTHER, DISORDERS	Placebo							1	1.0	1.00	1	1.1	1.00						
	Imipramine																		
HEARING AND VESTIBULAR DISORDERS	Imipramine	1	0.9	1.00	2	1.9	1.00	1	1.0	1.00	1	1.0	1.00						
	Imipramine																		
LIVER AND BILIAR SYSTEM DISORDERS	Imipramine																		
	Reboxetine							1	1.0	1.00	1	1.0	1.00						
HEMATOLOGY DISORDERS	Imipramine																		
	Placebo																1	1.1	1.00
RESISTANCE MECHANISM DISORDERS	Placebo																1	1.1	1.00
	Imipramine																		

(*) number of adverse events on number of patient who complained of adverse events

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 63
ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Relationship																								
	Definite			Probable			Possible			Doubtful			None			Unknown			Missing			Total			
	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	
420 Total adverse events	6	4.3	22	15.6	52	36.9	26	18.4	17	12.1	15	10.6	3	2.1	144	100.0									
	5	2.4	24	11.4	103	48.8	41	19.4	23	10.9	8	3.8	7	3.3	211	100.0									
	6	2.1	64	22.2	153	53.1	26	9.0	9	3.1	20	6.9	10	3.5	288	100.0									
	3	20.0	3	20.0	8	53.3	1	6.7							15	100.0									
	1	3.4	7	24.1	18	62.1	2	6.9			1	3.4			29	100.0									
	1	1.9	18	34.0	31	58.5	1	1.9			1	1.9	1	1.9	53	100.0									
			4	25.0	8	50.0	4	25.0							16	100.0									
			1	9.1	7	63.6	1	9.1	2	18.2					11	100.0									
			3	13.6	13	59.1	2	9.1			3	13.6	1	4.5	22	100.0									
	1	33.3	1	33.3			1	33.3							3	100.0									
			4	26.7	7	46.7	2	13.3							1	6.7	15	100.0							
	1	3.8	9	34.6	11	42.3	2	7.7	2	7.7					26	100.0									
			3	50.0	2	33.3			1	16.7					6	100.0									
	1	5.0	3	15.0	8	40.0	8	40.0							20	100.0									
			6	33.3	9	50.0	2	11.1							1	5.6	18	100.0							
					5	83.3									1	16.7	6	100.0							
			2	16.7	6	50.0	2	16.7							1	8.3	12	100.0							
	3	12.0	4	16.0	16	64.0	1	4.0							25	100.0									
					2	20.0	6	60.0	2	20.0					10	100.0									
					7	36.8	8	42.1	3	15.8	1	5.3			19	100.0									
					3	33.3	5	55.6	1	11.1					9	100.0									
			1	20.0	1	20.0	1	20.0			2	40.0			5	100.0									

(CONTINUED)
(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 63

ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Relationship																																
	Definite			Probable			Possible			Doubtful			None			Unknown			Missing			Total											
	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%									
TREND	Reboxetine			5		89.3	1		16.7													6		100.0									
	Imipramine			11		55.0	2		10.0													1		5.0									
	Placebo			2		18.2	5		45.5	3		27.3										1		9.1									
AGITATION / ANXIETY / NERVOUSNESS	Reboxetine			11		84.6	2		15.4															13		100.0							
	Imipramine			1		20.0	2		40.0																	5		100.0					
	Placebo			1		25.0	1		25.0																		4		100.0				
INSOMNIA	Reboxetine			6		50.0	4		33.3																			12		100.0			
	Imipramine			6		75.0																						8		100.0			
	Placebo			2		66.7																						3		100.0			
BLURRED VISION	Reboxetine			1		14.3	3		42.9	1		14.3																7		100.0			
	Imipramine			4		36.4	4		36.4	3		27.3																	11		100.0		
	Placebo			4		40.0	5		50.0	1		10.0																	10		100.0		
SOMNOLENCE	Reboxetine			1		100.0																							1		100.0		
	Imipramine			4		66.7	2		33.3																					6		100.0	
	Placebo			3		75.0	1		25.0																					4		100.0	
ASTHENIA / FATIGUE	Reboxetine			1		25.0	2		50.0	1		25.0																		4		100.0	
	Imipramine			7		100.0																								7		100.0	
	Reboxetine			4		80.0	1		20.0																					5		100.0	
VERTIGO	Imipramine			1		12.5	6		75.0																					8		100.0	
	Placebo			1		50.0																								2		100.0	
	Reboxetine			1		50.0	1		50.0																						2		100.0
PARAESTHESIA	Imipramine			3		50.0	1		16.7																					6		100.0	
	Reboxetine			1		16.7																									1		16.7
	Placebo			1		16.7																									1		16.7

(CONTINUED)

(some adverse events are grouped in cluster)

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 63

ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Relationship																									
	Definite			Probable			Possible			Doubtful			None			Unknown			Missing			Total				
	No.	%		No.	%		No.	%		No.	%		No.	%		No.	%		No.	%		No.	%			
URINARY HESITANCY / RETENTION	1	50.0																								
	2	33.3	1	16.7	2	33.3	1	16.7																		
ABDOMINAL PAIN																										
SUICIDE ATTEMPT																										
FLUSHING / HOT FLUSHES																										
TACHYCARDIA																										
DYSPNOEA																										
RHINITIS																										
URINARY TRACT INFECTION																										
PALPITATION																										

(CONTINUED)

(some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 63

ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Relationship																
	Definite		Probable		Possible		Doubtful		None		Unknown		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
PALPITATION	Reboxetine					1	100.0									1	100.0
	Imipramine					2	100.0									2	100.0
ERYTHEMA / RASH	Placebo					1	50.0	1	50.0							2	100.0
	Reboxetine					1	100.0									1	100.0
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Imipramine										1	100.0				1	100.0
	Placebo																
CONFUSION	Imipramine					1	50.0									1	100.0
	Reboxetine					1	100.0									1	100.0
APPETITE INCREASED	Imipramine							1	50.0							1	100.0
	Placebo					1	100.0									1	100.0
WEIGHT INCREASE	Imipramine					1	50.0									1	100.0
	Reboxetine					1	100.0									1	100.0
HYPERKINESIA	Imipramine					1	50.0									1	100.0
	Placebo					2	100.0									2	100.0
MUSCLE CONTRACTIONS INVOLUNTARY	Imipramine					1	100.0									1	100.0
	Reboxetine					1	100.0									1	100.0
DIARRHOEA	Imipramine					1	50.0	1	50.0							2	100.0
	Placebo					2	66.7	1	33.3							3	100.0
NYALGIA	Imipramine					1	50.0									1	100.0
	Placebo																
DYSURIA	Reboxetine					1	50.0	1	50.0							2	100.0
	Imipramine					1	100.0									1	100.0

(CONTINUED)
(some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 63
ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

424

Adverse events/Assigned treatment	Relationship																
	Definite		Probable		Possible		Doubtful		None		Unknown		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
SINUSITIS	Placebo														1	100.0	
	Reboxetine										1	100.0			2	100.0	
INFLUENZA-LIKE SYMPTOMS	Placebo								2	100.0					1	100.0	
	Reboxetine													1	100.0	1	100.0
TINNITUS	Imipramine													1	100.0	1	100.0
	Imipramine	1	50.0			1	50.0								2	100.0	
CHEST PAIN	Reboxetine															1	100.0
	Imipramine															1	100.0
CONJUNCTIVITIS	Imipramine															1	100.0
	Imipramine										1	50.0			2	100.0	
HYPERTENSION	Reboxetine															1	100.0
	Imipramine															1	100.0
INCREASED LIVER ENZYMES	Reboxetine															1	100.0
	Imipramine															1	100.0
WEIGHT DECREASE	Placebo															1	100.0
	Reboxetine														1	100.0	
HYDRIASIS	Reboxetine															2	100.0
	Placebo															1	100.0
ASTHMA	Reboxetine															1	100.0
	Placebo															1	100.0
BACK PAIN	Reboxetine															1	100.0
	Placebo														2	100.0	
IMPOTENCE	Reboxetine															1	100.0
	Reboxetine	1	100.0													1	100.0

(CONTINUED)
(some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No. : 63

ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Relationship																											
	Definite			Probable			Possible			Doubtful			None			Unknown			Missing			Total						
	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%				
BRADYCARDIA				1	100.0																			1	100.0			
TASTE LOSS				1	100.0																				1	100.0		
SALIVA INCREASED									1	100.0																1	100.0	
EXTRASYSTOLES									1	100.0																1	100.0	
SPEECH DISORDER									1	100.0																1	100.0	
EOSINOPHILIA									1	100.0																1	100.0	
HYPERURICASMIA									1	100.0																1	100.0	
PHOSPHATASE ALKALINE INCREASED									1	100.0																1	100.0	
CONCENTRATION IMPAIRED									1	100.0																1	100.0	
DEPERSONALIZATION									1	100.0																1	100.0	
SLEEP DISORDER									1	100.0																1	100.0	
MICTURITION FREQUENCY									1	100.0																1	100.0	
ANEMIA													1	100.0												1	100.0	
LIBIDO DECREASED													1	100.0												1	100.0	
PERINEAL PAIN MALE													1	100.0												1	100.0	
HYPERPYREXIA																												
HAEMORRHOIDS THROMBOSIS																												
ANDREXIA																												
GASTROENTERITIS																												
TONGUE ULCERATION																												
AUTOLESIONIST BEHAVIOUR																												

(CONTINUED)

(some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 63
ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

426

Adverse events/Assigned treatment	Relationship																	
	Definite		Probable		Possible		Doubtful		None		Unknown		Missing		Total			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%		
DEPRESSION AGGRAVATED																1	100.0	
EPIDIDYMITIS																1	100.0	
HERPES SIMPLEX																1	100.0	
BRONCHITIS																1	100.0	
PHARYNGITIS																1	100.0	
RHAGADES																1	100.0	
PYURIA																1	100.0	
CHROMATOPSIA																1	100.0	
MALAISE																1	100.0	
RIGORS																1	100.0	
HYPERTONIA																1	100.0	
COLITIS																1	100.0	
DUODENAL ULCER REACTIVATED																1	100.0	
DYSFHAGIA																1	100.0	
HYPERTRIGLYCERIDAEMIA																1	100.0	
HYPOKALAEMIA																1	100.0	
PANORRHEA																1	100.0	
COLD URTICARIA																1	100.0	
TASTE PERVERSION																1	100.0	
EYE ABNORMALITY																1	100.0	
TOOTH DISORDER															1	100.0	1	100.0

(some adverse events are grouped in cluster)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 64

ADVERSE EVENTS(*) PRESENT AT LAST DAY OF TREATMENT AND THEIR RELATIONSHIP TO STUDY MEDICATION
(ONLY PATIENTS WHO WITHDREW FROM THE STUDY FOR ADVERSE EVENTS)

All adverse events	Ass. treatment	Days of Treatment	Relationship							Total
			Possible	Doubtful	Probable	Definite	Unknown	None	Missing	
	Placebo		11	2	2	2	2	3	2	22
	Imipramine		28	1	6	3	6	6	3	47
	Reboxetine		15	2	8	3	3		3	31
Centre - Patient	Adverse events	Ass. treatment								
1 - 6 (Female)	RASH	Placebo	1							1
	ARTHRALGIA	Placebo		1						1
	CONSTIPATION	Placebo			1					1
	MOUTH DRY	Placebo				1				1
	TASTE PERVERSION	Placebo						1		1
	PARONYCHIA	Placebo						1		1
	ABDOMINAL PAIN	Placebo	1							1
	FLATULENCE	Placebo		1						1
	NAUSEA	Placebo	1							1
	MICTURITION DISORDER	Placebo								1
1 - 11 (Female)	DIZZINESS	Imipramine					1			1
	HYPOTENSION POSTURAL	Imipramine					1			1
3/1 - 143 (Female)	SWEATING INCREASED	Reboxetine			1					1
	DISPNOEA	Reboxetine	1							1
3/1 - 451 (Female)	CONSTIPATION	Reboxetine				1				1
	HAEMORRHOIDS THROMBOSED	Reboxetine							1	1

427

(*) Only adverse events complained on the last day of treatment and still present or resulting in withdrawal
(CONTINUED)

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No. : 64

ADVERSE EVENTS (*) PRESENT AT LAST DAY OF TREATMENT AND THEIR RELATIONSHIP TO STUDY MEDICATION
(ONLY PATIENTS WHO WITHDREW FROM THE STUDY FOR ADVERSE EVENTS)

Centre - Patient	Days of Treatment	Adverse events	Ass. treatment	Relationship						Total
				Possible	Doubtful	Probable	Definite	Unknown	None	
3/4 - 456 (Female)	10	CONSTIPATION	Imipramine			1				1
		MOUTH DRY	Imipramine			1				1
		SWEATING INCREASED	Imipramine			1				1
		TACHYCARDIA	Imipramine			1				1
428		SYNCOPE	Imipramine	1						1
		CHEST PAIN PRECORDIAL	Imipramine	1						1
		DIZZINESS	Imipramine	1						1
3/4 - 80 (Male)	24	VISION ABNORMAL	Imipramine	1					1	
3/4 - 83 (Male)	8	TREMOR	Placebo	1						1
		AGITATION	Placebo	1						1
		DIARRHOEA	Placebo	1						1
		INSOMNIA	Placebo	1						1
3/4 - 460 (Male)	2	MOUTH DRY	Reboxetine			1				1
		CONFUSION	Reboxetine			1				1
3/4 - 461 (Female)	8	MOUTH DRY	Imipramine	1						1
		NAUSEA	Imipramine	1						1
		DIZZINESS	Imipramine	1						1
		INSOMNIA	Imipramine	1						1
3/4 - 462 (Female)	10	HYPKINESIA	Imipramine	1						1
		DEPERSONALIZATION	Imipramine	1						1
		NAUSEA	Imipramine	1						1
4/1 - 116 (Female)	7			1					1	

(CONTINUED)

(*) Only adverse events complained on the last day of treatment and still present or resulting in withdrawal

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012/4/015
TABLE No.: 64

ADVERSE EVENTS(*) PRESENT AT LAST DAY OF TREATMENT AND THEIR RELATIONSHIP TO STUDY MEDICATION
(ONLY PATIENTS WHO WITHDREW FROM THE STUDY FOR ADVERSE EVENTS)

Centre - Patient	Days of Treatment	Adverse events	Ass. treatment	Relationship							Total	
				Possible	Doubtful	Probable	Definite	Unknown	None	Missing		
4/1 - 116 (Female)	7	HEADACHE	Imipramine	1								1
		VERTIGO	Imipramine	1								1
4/3 - 99 (Female)	8	DIARRHOEA	Placebo	1								1
		DISPEPSIA	Placebo	1								1
4/3 - 100 (Female)	21	NAUSEA	Imipramine	1								1
		SWEATING INCREASED	Imipramine	1								1
429		TREMOR	Imipramine	1								1
		VERTIGO	Imipramine	1								1
		SUICIDE ATTEMPT	Placebo	1						1		1
4/4 - 176 (Female)	26	DEPRESSION AGGRAVATED	Placebo							1		1
		SUICIDE ATTEMPT	Placebo						1			1
4/4 - 179 (Female)	19	MOUTH DRY	Imipramine	1								1
		HYPOTENSION POSTURAL	Imipramine	1								1
6/1 - 151 (Male)	8	SWEATING INCREASED	Imipramine	1								1
		ASTHENIA	Imipramine	1								1
6/2 - 161 (Female)	28	MOUTH DRY	Reboxetine	1								1
		URINARY TRACT INFECTION	Reboxetine							1		1
6/3 - 163 (Male)	3	TACHYCARDIA	Reboxetine	1								1
		VERTIGO	Reboxetine	1								1
		ANXIETY	Reboxetine	1								1

(CONTINUED)

(*) Only adverse events complained on the last day of treatment and still present or resulting in withdrawal

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 64

ADVERSE EVENTS(*) PRESENT AT LAST DAY OF TREATMENT AND THEIR RELATIONSHIP TO STUDY MEDICATION
(ONLY PATIENTS WHO WITHDREW FROM THE STUDY FOR ADVERSE EVENTS)

Centre - Patient	Days of Treatment	Adverse events	Ass. treatment	Relationship						Total	
				Possible	Doubtful	Probable	Definite	Unknown	None		Missing
6/3 - 510 (Female)	13	INSOMNIA	Reboxetine	1							1
		VERTIGO	Reboxetine	1							1
		HYPOTENSION	Reboxetine			1					1
7/02 - 183 (Male)	17	ABDOMINAL PAIN	Imipramine						1		1
		SWEATING INCREASED	Imipramine	1							1
		TREMOR	Imipramine					1			1
		AGITATION	Imipramine					1			1
		PARAESTHESIA	Imipramine					1			1
		TINNITUS	Imipramine				1				1
		COLITIS	Imipramine					1			1
		DYSPHAGIA	Imipramine					1			1
		RIGORS	Imipramine					1			1
		URINARY RETENTION	Reboxetine				1				1
7/02 - 185 (Male)	26	GAMMA-GT INCREASED	Reboxetine		1						1
		IMPOTENCE	Reboxetine				1			1	
		SUICIDE ATTEMPT	Imipramine						1		1
7/03 - 191 (Female)	3	SUICIDE ATTEMPT	Imipramine						1		1
		SUICIDE ATTEMPT	Imipramine						1		1
8 - 213 (Male)	3	SUICIDE ATTEMPT	Imipramine						1		1
		AGITATION	Placebo	1							1
9 - 241 (Female)	11	HYPERKINESIA	Placebo	1							1
		BRADYCARDIA	Placebo			1					1
9 - 246 (Female)	24	BRADYCARDIA	Placebo				1				1
		MOUTH DRY	Reboxetine	1							1

(CONTINUED)

(*) Only adverse events complained on the last day of treatment and still present or resulting in withdrawal

9550082

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 64

ADVERSE EVENTS (*) PRESENT AT LAST DAY OF TREATMENT AND THEIR RELATIONSHIP TO STUDY MEDICATION
(ONLY PATIENTS WHO WITHDREW FROM THE STUDY FOR ADVERSE EVENTS)

4
3
1

Centre - Patient	Days of Treatment	Adverse events	Ass. treatment	Relationship						Total	
				Possible	Doubtful	Probable	Definite	Unknown	None		Missing
9 - 252 (Female)	19	TREMOR	Reboxetine	1							1
		AGITATION	Reboxetine	1							1
		MUSCLE CONTRACTIONS INVOLUNTARY	Reboxetine	1							1
9 - 253 (Female)	7	AGITATION	Reboxetine	1							1
9 - 254 (Female)	8	MOUTH DRY	Imipramine	1							1
		TREMOR	Imipramine	1							1
9 - 255 (Female)	25	INSOMNIA	Imipramine	1							1
		MOUTH DRY	Reboxetine	2							2
		AGITATION	Reboxetine	1							1
		DIARRHOEA	Reboxetine	1							1
11 - 334 (Female)	9	PYURIA	Reboxetine							1	1
		DIZZINESS	Reboxetine						1		1
		SWEATING INCREASED	Reboxetine						1		1
		PARAESTHESIA	Reboxetine						1		1
		CHEST PAIN	Reboxetine						1		1
		MOUTH DRY	Imipramine	1							1
12 - 371 (Female)	6	VISION ABNORMAL	Imipramine								1
		SUICIDE ATTEMPT	Imipramine	1							1
13 - 46 (Male)	45	NAUSEA	Imipramine	1							1
		SWEATING INCREASED	Imipramine						1		1

(CONTINUED)

(*) Only adverse events complained on the last day of treatment and still present or resulting in withdrawal

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 64

ADVERSE EVENTS(*) PRESENT AT LAST DAY OF TREATMENT AND THEIR RELATIONSHIP TO STUDY MEDICATION
(ONLY PATIENTS WHO WITHDREW FROM THE STUDY FOR ADVERSE EVENTS)

Centre - Patient	Days of Treatment	Adverse events	Ass. treatment	Relationship					Total		
				Possible	Doubtful	Probable	Definite	Unknown		None	Missing
13 - 16 (Male)	45	HOT FLUSHES	Imipramine				1				1

432

(*) Only adverse events complained on the last day of treatment and still present or resulting in withdrawal

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 65
LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Imipramine						Placebo						Reboxetine					
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
HB	Evaluated	87	78	70	98	92	81	86	79									
	Mean	14.13	14.15	13.98	14.62	14.47	14.47	14.22	14.33									
	STD	1.74	2.00	1.83	1.55	1.43	1.72	1.68	1.55									
	Min	10.63	10.21	10.42	12.00	12.00	11.42	9.40	11.07									
	Max	23.39	25.06	23.61	22.28	20.83	22.72	19.50	18.03	19.10								
	Median	14.00	14.00	13.68	14.58	14.34	14.10	13.99	14.30	14.20								
	Median diff.		0.16	-0.09		-0.07	-0.29		0.00	0.07								
P value		0.2894	0.7270		0.1157	0.1248		0.6914	0.5953									
HT	Evaluated	84	73	67	89	83	72	83	70									
	Mean	41.16	40.91	40.89	42.68	42.59	42.25	41.99	42.23									
	STD	5.21	4.84	4.96	4.47	4.28	4.64	4.61	4.29									
	Min	31.89	31.33	30.90	32.10	34.80	32.59	31.90	34.00	32.00								
	Max	54.92	53.00	57.56	51.71	54.54	52.50	53.00	51.29	50.26								
	Median	40.00	40.59	40.00	42.41	41.84	41.28	40.75	42.05	41.78								
	Median diff.		0.53	0.25		-0.08	0.00		0.11	-0.41								
P value		0.0731	0.9899		0.6430	0.3024		0.7196	0.3306									
RBC	Evaluated	87	77	69	98	92	81	93	80									
	Mean	4.60	4.63	4.57	4.82	4.81	4.83	4.67	4.71									
	STD	0.59	0.57	0.51	0.59	0.59	0.78	0.65	0.59	0.56								
	Min	2.89	3.50	3.38	3.89	3.71	2.88	2.38	3.40	3.56								
	Max	5.93	6.12	5.86	6.90	6.54	8.33	6.73	6.68	6.40								

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P VALUE: PROBABILITY FROM THE MILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 65

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																						
	Imipramine				Placebo				Reboxetine														
	Days of treatment			Screen	Days of treatment			Screen	Days of treatment			Screen											
	1-21	22-42	4.56		1-21	22-42	4.70		1-21	22-42	4.70												
RBC	4.55	4.56	4.53	4.79	4.70	4.70	4.63	4.70	4.70	4.70	4.73	0.00	-0.00	0.9094	0.4517	0.9094	75	75	254.50	254.50	79.44	79.44	
Median	0.06	0.02	0.02		0.01	-0.02																	
Median diff.	0.1507	0.9882	0.9882		0.4240	0.6181																	
P value	83	73	66	93	89	74	88	74	88	79	75	88	74	88	79	75	88	74	88	79	75	88	74
Evaluated	272.00	274.27	281.18	259.35	253.86	258.74	255.33	258.74	255.33	262.11	254.50	255.33	258.74	255.33	262.11	254.50	255.33	258.74	255.33	262.11	254.50	255.33	258.74
Mean	71.57	68.15	69.74	72.15	68.04	79.19	70.68	79.19	70.68	70.35	79.44	70.68	79.19	70.68	70.35	79.44	70.68	79.19	70.68	70.35	79.44	70.68	79.19
STD	20.00	75.00	92.50	-97.50	-90.00	-82.50	50.00	-82.50	50.00	107.50	43.75	50.00	-82.50	50.00	107.50	43.75	50.00	-82.50	50.00	107.50	43.75	50.00	-82.50
Min	504.00	468.75	470.00	409.00	438.33	486.21	403.00	438.33	486.21	403.00	490.00	403.00	438.33	486.21	403.00	490.00	403.00	438.33	486.21	403.00	490.00	403.00	438.33
Max	267.65	274.00	287.83	260.06	250.83	252.89	257.00	250.83	252.89	271.00	254.00	257.00	250.83	252.89	271.00	254.00	257.00	250.83	252.89	271.00	254.00	257.00	250.83
Median		-5.00	5.92		-5.00	-0.96				2.78	0.00				2.78	0.00				2.78	0.00		
Median diff.	0.6748	0.1615	0.1615		0.2145	0.6553				0.6130	0.6202				0.6130	0.6202				0.6130	0.6202		
P value																							

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 65
LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment												
	Imipramine				Placebo				Reboxetine				
	Days of treatment			Screen	Days of treatment			Screen	Days of treatment			Screen	
WBC	Evaluated	87	78	70	98	92	81	93	87	80	80	87	80
	Mean	7.26	7.22	7.07	7.97	7.55	7.78	7.25	7.50	7.40	7.40	7.50	7.40
	STD	2.09	2.16	2.25	2.49	2.20	2.19	2.27	2.59	2.09	2.09	2.59	2.09
	Min	-0.07	1.66	1.41	3.33	3.30	3.31	2.44	4.50	3.09	3.09	4.50	3.09
	Max	11.14	13.06	15.23	17.40	16.49	13.92	13.97	20.86	13.48	13.48	20.86	13.48
	Median	6.99	7.17	7.00	7.58	7.43	7.75	6.84	7.01	7.10	7.10	7.01	7.10
	Median diff.		-0.17	-0.11		-0.28	-0.37		0.35	0.52	0.52	0.35	0.52
P value		0.6517	0.6809		0.0904	0.1361		0.0928	0.0389	0.0389	0.0928	0.0389	
WBC: N	Evaluated	81	71	67	93	85	78	88	79	79	79	79	79
	Mean	61.26	62.43	61.80	61.79	61.52	61.79	61.35	61.57	62.42	62.42	61.57	62.42
	STD	5.24	5.13	4.12	3.75	4.09	3.71	7.12	5.72	5.02	5.02	5.72	5.02
	Min	44.14	44.14	51.00	52.71	48.43	54.65	29.86	31.29	38.43	38.43	31.29	38.43
	Max	82.71	79.86	69.55	75.57	70.25	74.14	94.14	79.00	78.43	78.43	79.00	78.43
	Median	61.84	62.78	62.41	62.00	61.33	61.96	61.57	62.00	62.65	62.65	61.57	62.65
	Median diff.		0.00	0.06		-0.20	-0.50		0.00	0.50	0.50	0.00	0.50
P value		0.1283	0.1294		0.6640	0.2204		0.4949	0.1113	0.1113	0.4949	0.1113	
WBC: E	Evaluated	80	70	65	92	84	77	87	77	78	77	77	78
	Mean	1.65	1.75	1.82	1.94	1.68	1.76	1.62	1.89	1.76	1.76	1.89	1.76
	STD	0.97	1.34	1.26	1.48	1.11	1.07	1.15	1.35	1.20	1.20	1.35	1.20
	Min	0.00	0.00	0.00	-1.00	-1.00	0.00	-1.00	-1.00	-1.00	-1.00	-1.00	-1.00
	Max	7.00	8.56	7.92	9.71	6.00	5.29	7.00	7.00	7.00	7.00	7.00	7.00
	Median												
	Median diff.												

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 65
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Imipramine						Placebo						Reboxetine					
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
HBC: E	Median	1.46	1.59	1.50	1.67	1.50	1.50	1.50	1.55	1.50	1.60	1.57	1.50	1.60	1.57	1.50	1.60	1.57
	Median diff.		0.00	0.00			0.00	0.00			0.00	0.00			0.00	0.00	0.00	
	P value		0.9875	0.7205			0.0357	0.5127			0.0569	0.1107			0.0569	0.1107		
	Evaluated	78	67	64	90	82	73	86	77	77	77	77	77	77	77	77	77	77
HBC: B	Mean	0.28	0.25	0.31	0.26	0.19	0.27	0.20	0.26	0.26	0.26	0.28	0.20	0.26	0.26	0.26	0.26	0.28
	STD	0.34	0.32	0.34	0.30	0.26	0.40	0.27	0.37	0.36	0.37	0.36	0.27	0.37	0.37	0.37	0.37	0.36
	Min	0.00	-0.38	-0.08	-0.02	-0.08	-0.03	-0.08	-0.08	-0.08	-0.08	-0.08	0.00	-0.08	-0.08	-0.08	-0.08	0.00
	Max	2.06	1.50	1.72	1.50	1.13	2.25	0.75	1.50	1.50	1.50	1.50	1.50	0.75	1.50	1.50	1.50	1.50
HBC: L	Median	0.25	0.19	0.25	0.19	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Median diff.		0.00	0.00			0.00	0.00			0.00	0.00			0.00	0.00	0.00	
	P value		0.9882	0.4144			0.0926	0.4861			0.5995	0.1019			0.5995	0.1019		
	Evaluated	87	76	70	98	91	81	91	82	79	82	79	91	82	79	82	79	79
HBC: H	Mean	28.43	26.99	27.67	28.37	28.63	28.25	28.80	28.21	28.11	28.21	28.11	28.80	28.21	28.11	28.80	28.21	28.11
	STD	5.24	5.21	4.97	4.74	4.96	4.53	5.79	4.47	4.60	4.47	4.60	5.79	4.47	4.60	5.79	4.47	4.60
	Min	17.67	15.75	18.55	19.80	15.33	17.80	14.33	17.10	18.60	17.10	18.60	14.33	17.10	18.60	14.33	17.10	18.60
	Max	40.56	43.00	40.17	47.00	49.29	43.00	45.67	43.00	45.67	43.00	45.67	43.00	45.67	43.00	45.67	43.00	45.67
HBC: N	Median	27.80	26.58	26.47	28.35	28.53	27.40	28.33	27.70	27.83	27.70	27.83	28.33	27.70	27.83	28.33	27.70	27.83
	Median diff.		-1.00	-0.44			0.71	0.00			-0.14	-0.40			-0.14	-0.40		
	P value		0.0008	0.0824			0.2852	0.8801			0.2796	0.2519			0.2796	0.2519		
	Evaluated	87	75	70	98	91	81	91	81	79	81	79	91	81	79	81	79	79
HBC: M	Mean	4.24	4.24	4.36	4.74	4.52	4.63	4.47	4.67	4.47	4.67	4.47	4.67	4.47	4.67	4.47	4.67	4.47
	Median	4.24	4.24	4.36	4.74	4.52	4.63	4.47	4.67	4.47	4.67	4.47	4.67	4.47	4.67	4.47	4.67	4.47

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 65
LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Imipramine						Placebo						Reboxetine					
	Days of treatment		22-42		1-21		Days of treatment		22-42		1-21		Days of treatment		22-42		1-21	
WBC: K	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
STD		2.08	1.86	2.01	2.00	1.46	1.73	2.00	2.11	2.30	0.00	0.00	11.00	15.00	4.26	4.47	0.20	0.00
Min		-3.60	-1.20	-2.20	0.00	1.27	0.00	0.00	8.14	9.29	4.33	4.47	4.21	4.26	4.47	0.20	0.00	0.00
Max		10.50	11.00	10.54	13.00	8.14	9.29	4.39	4.33	4.47	4.21	4.26	4.47	0.20	0.00	0.00	0.00	0.00
Median		4.21	4.30	4.29	4.39	4.33	4.47	4.39	4.33	4.47	4.21	4.26	4.47	0.20	0.00	0.00	0.00	0.00
Median diff.			0.00	0.00		0.00	0.00		0.00	0.00		0.00		0.00	0.00		0.00	0.00
P value			0.9892	0.7517		0.4819	0.8810		0.4819	0.8810		0.2049		0.2120				

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOSETINE - PROTOCOL 20124/015
 TABLE No.: 55
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Imipramine				Placebo				Rebosetine			
	Days of treatment		Days of treatment		Days of treatment		Days of treatment		Days of treatment		Days of treatment	
	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen
CREATININE	Evaluated	84	75	97	91	77	94	88	84			
	Mean	0.85	0.86	0.90	0.89	0.86	0.85	0.85	0.86			
	STD	0.20	0.24	0.22	0.22	0.20	0.22	0.23	0.23			
	Min	0.35	0.40	0.37	0.40	0.50	0.26	0.24	0.40			
	Max	1.40	1.79	1.54	1.41	1.30	1.64	1.69	1.57			
	Median	0.82	0.84	0.86	0.90	0.81	0.85	0.82	0.86			
UREA	Median diff.	0.03	0.00		0.00	-0.01		0.00	-0.01			
	P value	0.0064	0.6598		0.4993	0.2075		0.3067	0.2133			
	Evaluated	54	48	44	56	41	56	51	49			
	Mean	24.62	23.77	24.96	26.07	24.03	22.05	23.27	22.56			
	STD	6.01	6.63	6.60	5.52	6.35	7.63	5.21	5.99			
	Min	10.90	12.31	10.86	16.13	14.57	7.00	13.86	9.86			
BUN	Max	39.40	43.00	43.00	38.91	37.61	41.00	35.40	40.22			
	Median	24.20	23.23	24.35	26.87	24.33	21.53	23.11	21.80			
	Median diff.	-1.20	-0.75		-0.83	-1.20		1.51	-0.30			
	P value	0.3545	0.6377		0.5955	0.0883		0.1904	0.8065			
	Evaluated	32	31	24	35	29	37	36	29			
	Mean	11.90	13.10	12.88	12.95	13.37	13.47	13.44	14.01			
STD	2.14	3.10	2.63	3.92	2.61	3.16	3.26	4.65				
Min	7.00	6.18	7.70	7.70	8.22	7.58	7.70	8.10				
Max	15.80	21.03	16.90	28.44	18.83	22.13	21.85	30.83				

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P VALUE: PROBABILITY FROM THE MILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D

REBOXYLINE - PROTOCOL 20124/015
TABLE No.: 65

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Imipramine						Placebo					
	Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
BUN	Median	11.72	13.21	12.64	13.08	12.50	13.49	13.08	13.33	13.68		
	Median diff.		0.55	1.24		0.58	0.83		0.27	0.00		
	P value		0.0331	0.0490		0.3797	0.0897		0.5201	0.7310		
URIC ACID	Evaluated	80	72	65	90	85	76	86	79	79		
	Mean	4.58	4.59	4.90	5.02	5.15	5.06	4.86	5.05	5.00		
	STD	1.62	1.55	1.72	1.46	1.61	1.64	1.56	1.72	1.54		
	Min	0.24	0.33	0.24	1.50	2.25	2.43	1.42	0.56	1.60		
	Max	8.64	8.27	9.89	8.57	9.44	11.57	7.83	10.42	9.63		
	Median	4.36	4.56	4.68	4.91	5.10	4.90	4.88	4.98	4.88		
	Median diff.		0.11	0.00		0.15	-0.06		0.10	0.00		
	P value		0.1222	0.3169		0.1935	0.8561		0.4934	0.3415		

P VALUE: PROBABILITY FROM THE MILCOXON RANK SIGNED TEST

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PHARNACIA CNS RED
REBOXETINE - PROTOCOL 2012/015
TABLE No. : 65
LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment														
	Imipramine					Placebo					Reboxetine				
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
TOT. PROTEINS	Evaluated	88	81	70	92	88	73	81	92	87	81				
	Mean	7.40	7.41	7.52	7.36	7.31	7.36	7.41	7.38	7.41	7.37				
	STD	0.62	0.59	0.64	0.59	0.58	0.58	0.64	0.64	0.68	0.58				
	Min	5.62	5.26	5.77	5.77	6.02	6.06	5.95	4.63	4.88					
	Max	8.71	8.93	9.09	8.68	8.84	8.64	9.65	9.41	8.78					
	Median	7.45	7.35	7.43	7.38	7.30	7.31	7.35	7.40	7.41					
Median diff.		0.07	0.00		-0.09	0.00		0.08	0.07						
P value		0.4259	0.2741		0.3756	0.7078		0.3321	0.2976						
ALBUMINE	Evaluated	87	81	67	93	88	73	89	81	79					
	Mean	4.61	4.60	4.62	4.53	4.59	4.61	4.44	4.43	4.24					
	STD	1.14	0.94	0.95	0.96	0.94	1.03	0.74	0.88	1.02					
	Min	1.08	3.14	1.42	1.63	1.66	0.91	2.53	1.51	0.61					
	Max	8.78	8.33	8.00	8.42	7.67	7.91	6.50	7.67	6.50					
	Median	4.42	4.49	4.58	4.40	4.54	4.50	4.34	4.42	4.31					
Median diff.		-0.06	0.00		0.00	-0.05		-0.10	-0.01						
P value		0.3498	0.5926		0.5119	0.8449		0.1869	0.0595						
TOT BILIRUBIN	Evaluated	88	81	72	95	91	73	93	89	82					
	Mean	0.58	0.51	0.55	0.59	0.60	0.54	0.63	0.58	0.57					
	STD	0.26	0.25	0.25	0.25	0.26	0.22	0.25	0.28	0.21					
	Min	0.20	0.15	0.09	0.10	0.15	0.20	0.20	0.20	0.20					
	Max	1.48	1.57	1.17	1.47	1.79	1.51	1.70	2.30	1.18					

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 65
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Imipramine				Placebo				Reboxetine			
	Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
TOT BILIRUBIN	Median	0.54	0.45	0.52	0.57	0.57	0.52	0.60	0.55	0.54		
	Median diff.		-0.04	-0.02		0.00	0.00		0.00	-0.01		
	P value		0.0147	0.1509		0.8177	0.3603		0.1234	0.0789		
DIR BILIRUBIN	Evaluated	34	31	26	39	38	31	39	36	31		
	Mean	0.08	0.08	0.07	0.10	0.12	0.11	0.13	0.09	0.09		
	STD	0.07	0.07	0.07	0.17	0.22	0.14	0.14	0.05	0.04		
	Min	0.00	0.00	-0.10	0.00	0.00	0.00	0.00	0.00	0.00		
	Max	0.36	0.32	0.24	1.09	1.41	0.85	0.84	0.24	0.17		
	Median	0.07	0.07	0.07	0.08	0.08	0.08	0.11	0.08	0.09		
	Median diff.			-0.00		0.00	0.00		-0.03	0.00		
	P value		0.4150	0.0616		0.4978	0.3889		0.0324	0.0338		

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 85
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Imipramine				Placebo				Reboxetine			
	Days of treatment				Days of treatment				Days of treatment			
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
SGOT	Evaluated	90	80	74	95	88	76	94	88	84		
	Mean	21.20	20.94	22.62	27.35	19.19	19.49	21.13	18.71	19.96		
	STD	15.96	13.34	12.93	72.73	6.36	6.45	10.16	4.89	6.68		
	Min	8.00	10.00	9.00	9.00	10.00	9.00	9.00	10.00	10.53		
	Max	142.00	124.00	100.00	725.00	53.33	50.00	80.00	34.42	54.32		
	Median	17.40	18.30	19.28	18.18	18.57	18.00	18.82	18.17	18.75		
	Median diff.		0.00	1.07		-0.60	-0.93		-0.56	0.00		
P value		0.4365	0.1199		0.3022	0.1130		0.1654	0.5011			
SGPT	Evaluated	84	75	68	88	81	69	89	84	79		
	Mean	16.87	17.86	20.82	22.51	17.56	15.68	16.37	14.92	16.15		
	STD	14.18	15.25	14.55	56.10	14.88	10.49	12.75	7.35	10.36		
	Min	1.43	2.50	5.00	5.00	0.83	3.33	2.50	2.50	3.33		
	Max	96.94	90.83	74.64	532.78	100.97	73.00	92.50	45.44	66.90		
	Median	14.20	13.57	17.11	13.06	14.38	13.00	13.13	14.19	13.82		
	Median diff.		0.00	2.57		-0.64	-1.39		0.00	0.50		
P value		0.3134	0.0125		0.3337	0.0228		0.3351	0.8373			
GAMMA GT	Evaluated	82	75	62	95	88	72	88	82	76		
	Mean	64.21	58.42	79.23	34.08	28.08	29.56	40.85	30.02	29.37		
	STD	204.06	212.31	205.93	33.58	19.31	17.82	69.43	27.09	21.12		
	Min	5.54	5.44	8.00	10.00	8.00	10.74	8.00	3.53	8.00		
	Max	1800.00	1846.77	1514.46	279.30	107.70	97.83	568.00	206.55	131.64		
	Median											
	Median diff.											

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 85
LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Imipramine				Placebo				Reboxetine			
	Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
GAMMA GT	Median	23.02	23.54	29.67	23.91	22.20	22.41	22.74	23.88	23.34		
	Median diff.		0.00	2.46		-1.91	-1.50		-1.71	-0.86		
	P value		0.9729	0.0558		0.0018	0.0224		0.0159	0.0919		
LDH	Evaluated	76	68	54	82	76	64	80	72	68		
	Mean	287.90	306.99	320.38	284.91	278.61	277.58	286.72	300.82	320.15		
	STD	107.60	125.18	108.99	149.42	138.62	119.19	128.69	137.54	131.08		
	Min	-90.00	-6.00	42.00	-99.00	-90.00	-150.00	-129.00	-48.00	-24.00		
	Max	539.00	667.75	688.33	1148.00	695.33	521.64	550.20	737.52	812.00		
	Median	301.03	303.37	320.92	291.39	281.81	292.08	298.59	297.65	298.67		
	Median diff.		6.50	16.99		-15.94	-13.22		9.23	12.21		
	P value		0.3600	0.0574		0.1219	0.5838		0.5512	0.1184		
ALK. PROSPH.	Evaluated	88	79	73	97	91	77	94	87	84		
	Mean	104.38	104.73	116.80	123.44	124.26	123.33	108.19	106.81	105.56		
	STD	44.44	40.78	52.10	151.82	148.88	162.27	40.87	40.78	38.07		
	Min	1.55	1.55	-8.35	46.10	41.15	46.10	39.20	36.35	35.13		
	Max	277.76	222.50	335.68	1561.94	1487.69	1497.21	246.58	231.73	229.25		
	Median	92.97	98.61	108.80	107.60	109.41	105.70	102.94	98.30	99.78		
	Median diff.		3.60	7.92		-3.26	-3.76		0.00	0.38		
	P value		0.4275	0.0046		0.0772	0.0802		0.9758	0.6046		

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
 ROBEXETINE - PROTOCOL 20124/015
 TABLE No.: 65
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Imipramine						Placebo						Roboxetine					
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
GLOBULINS ALPHA 1	Evaluated	67	59	49	71	67	54	60	67	59	60	67	59	60	67	59	60	60
	Mean	0.20	0.19	0.20	0.20	0.18	0.21	0.19	0.18	0.20	0.19	0.18	0.20	0.19	0.18	0.20	0.19	0.19
	STD	0.07	0.08	0.07	0.10	0.06	0.07	0.07	0.07	0.06	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07
	Min	0.06	0.06	0.07	0.03	0.05	0.06	-0.03	0.10	0.03	0.04	0.03	0.03	0.04	0.03	0.03	0.04	0.03
	Max	0.36	0.46	0.40	0.64	0.32	0.37	0.32	0.40	0.32	0.40	0.33	0.32	0.40	0.33	0.32	0.40	0.33
	Median	0.19	0.18	0.20	0.18	0.19	0.20	0.19	0.18	0.19	0.18	0.17	0.19	0.18	0.17	0.19	0.18	0.17
	Median diff.	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
P value	0.4154	0.1923	0.1923	0.8289	0.3122	0.8289	0.3122	0.8289	0.3122	0.8289	0.3122	0.8289	0.3122	0.8289	0.3122	0.8289	0.3122	
GLOBULINS ALPHA 2	Evaluated	67	59	49	71	67	54	60	67	59	60	67	59	60	67	59	60	60
	Mean	0.82	0.82	0.84	0.80	0.78	0.83	0.82	0.84	0.83	0.83	0.82	0.84	0.83	0.82	0.84	0.83	0.83
	STD	0.17	0.17	0.20	0.14	0.15	0.14	0.19	0.18	0.14	0.19	0.18	0.19	0.18	0.19	0.18	0.19	0.18
	Min	0.51	0.47	0.38	0.55	0.50	0.59	0.53	0.57	0.53	0.52	0.53	0.57	0.52	0.53	0.57	0.52	0.52
	Max	1.27	1.32	1.24	1.23	1.45	1.27	1.88	1.68	1.45	1.27	1.88	1.68	1.58	1.45	1.27	1.88	1.58
	Median	0.79	0.81	0.80	0.77	0.76	0.80	0.78	0.83	0.76	0.80	0.82	0.78	0.83	0.82	0.78	0.83	0.82
	Median diff.	-0.01	0.00	0.00	-0.01	0.00	-0.01	0.00	0.01	-0.01	0.00	0.01	0.01	0.00	0.01	0.01	0.00	0.00
P value	0.5883	0.4902	0.4902	0.5110	0.3613	0.5110	0.3613	0.5110	0.3613	0.5110	0.3613	0.5110	0.3613	0.5110	0.3613	0.5110	0.3613	
GLOBULINS BETA	Evaluated	67	59	49	71	67	54	60	67	59	60	67	59	60	67	59	60	60
	Mean	0.96	0.95	0.95	0.95	0.95	0.94	0.95	0.94	0.95	0.94	0.95	0.94	0.95	0.94	0.95	0.94	0.91
	STD	0.15	0.17	0.17	0.18	0.17	0.14	0.17	0.14	0.17	0.14	0.17	0.14	0.17	0.14	0.17	0.14	0.15
	Min	0.74	0.59	0.59	0.53	0.56	0.70	0.56	0.70	0.56	0.70	0.56	0.70	0.56	0.70	0.56	0.70	0.53
	Max	1.55	1.43	1.28	1.40	1.57	1.38	1.40	1.57	1.38	1.40	1.57	1.38	1.40	1.57	1.38	1.40	1.21

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No. : 65

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Imipramine						Placebo						Reboxetine					
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
GLOBULINS BETA	Median	0.94	0.94	0.95	0.94	0.94	0.90	0.93	0.92	0.94	0.92	0.94	0.92	0.94	0.92	0.94	0.92	0.92
	Median diff.		0.00	0.02		0.00	0.00	0.00		0.00	0.00		0.00	0.00		0.00	0.00	-0.01
	P value		0.7471	0.9460		0.7462	0.4376		0.9930	0.6117		0.9930	0.6117		0.9930	0.6117		0.6117
GLOBULINS GAMMA	Evaluated	67	59	49	71	54	67	54	67	59	60	60	59	60	60	59	60	60
	Mean	1.11	1.14	1.14	1.08	1.16	1.15	1.14	1.15	1.14	1.15	1.14	1.15	1.14	1.15	1.14	1.15	1.13
	STD	0.31	0.39	0.29	0.35	0.40	0.41	0.40	0.41	0.40	0.35	0.38	0.38	0.35	0.38	0.38	0.35	0.38
	Min	0.00	-0.43	0.27	0.45	0.53	0.45	0.13	0.45	0.13	0.11	-0.13	-0.13	0.11	-0.13	-0.13	0.11	-0.13
	Max	1.94	2.32	1.73	2.27	2.60	2.30	2.50	2.30	2.50	2.25	2.39	2.39	2.25	2.39	2.25	2.39	2.39
	Median	1.07	1.08	1.16	1.06	1.08	1.13	1.10	1.13	1.10	1.12	1.10	1.12	1.10	1.12	1.10	1.12	1.10
	Median diff.		0.00	0.01		0.07	0.09		0.05	0.05		-0.01	-0.01		-0.01	-0.01		-0.01
P value		0.3039	0.4475		0.0414	0.0415		0.3309	0.8365		0.8365	0.8365		0.8365	0.8365		0.8365	

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 65
LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																				
	Imipramine							Placebo							Reboxetine						
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment					
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42						
TOT. CHOLEST.	Evaluated	87	78	68	94	87	74	78	90	84	78	90	84	78							
	Mean	254.95	260.75	263.68	261.14	248.63	250.56	250.12	243.30	237.99	243.30	237.99	243.30	237.99							
	STD	74.68	71.87	75.76	66.95	61.29	65.28	66.84	60.81	67.71	60.81	67.71	60.81	67.71							
	Min	115.04	101.86	145.37	87.20	75.40	102.37	85.25	101.86	88.12	101.86	88.12	101.86	88.12							
	Max	515.47	455.08	540.46	458.06	450.70	479.70	444.32	395.18	421.12	395.18	421.12	395.18	421.12							
	Median	238.42	252.15	247.41	254.19	235.38	245.11	250.34	238.07	228.93	238.07	228.93	238.07	228.93							
Median diff.		7.60	5.12		-4.72	-10.00		-4.54	-10.88	-4.54	-10.88	-4.54	-10.88								
P value		0.4190	0.0817		0.1012	0.0094		0.1021	0.0080	0.1021	0.0080	0.1021	0.0080								
TRIGLYCERIDES	Evaluated	86	77	66	93	87	72	89	83	77	89	83	77								
	Mean	174.35	166.52	148.99	197.19	183.48	194.78	166.06	171.74	162.10	171.74	162.10	171.74								
	STD	129.67	138.23	98.71	176.27	136.16	188.95	115.19	169.21	119.71	169.21	119.71	169.21								
	Min	20.38	28.00	36.94	27.07	0.31	-22.98	-6.36	-8.65	-6.36	-8.65	-6.36	-8.65								
	Max	754.00	892.86	584.80	1266.73	714.83	1352.18	546.77	1330.82	583.09	1330.82	583.09	1330.82								
	Median	129.50	128.70	125.07	150.24	139.87	143.37	142.00	132.45	133.21	132.45	133.21	132.45								
Median diff.		1.81	-9.32		0.00	-0.39		-14.08	-2.22	-14.08	-2.22	-14.08									
P value		0.8288	0.0172		0.6172	0.6493		0.1066	0.3636	0.1066	0.3636	0.1066									
GLUCOSE	Evaluated	90	81	73	97	90	77	95	89	81	89	81	89								
	Mean	91.84	86.61	87.27	89.16	89.69	88.63	90.73	89.73	90.99	89.73	90.99	89.73								
	STD	24.05	13.99	12.30	10.94	12.48	14.82	15.10	14.96	17.24	14.96	17.24	14.96								
	Min	42.00	7.00	56.00	65.80	63.70	60.90	65.33	63.00	61.25	63.00	61.25	63.00								
	Max	282.33	117.73	119.70	117.89	136.82	154.88	148.24	147.21	142.53	147.21	142.53	147.21								
	Median																				

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P VALUE: PROBABILITY FROM THE MILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
 ROBEXETINE - PROTOCOL 20124/015
 TABLE No.: 65

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Imipramine						Placebo						Roboxetine					
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42			
GLUCOSE	90.24	85.75	86.00	87.50	89.59	86.80	87.50	89.59	86.80	87.50	88.35	85.75	88.35	85.75				
Median		-1.84	-3.89					1.48	0.00		1.56	-1.84						
Median diff.																		
P value		0.0408	0.0208		0.4123	0.8742		0.6543	0.6321									

P VALUE: PROBABILITY FROM THE MILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No. : 65
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Imipramine						Reboxetine					
	Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
NA+	Evaluated	90	82	73	96	90	77	96	90	84	84	
	Mean	140.54	139.61	140.09	141.17	140.65	140.60	140.78	140.46	140.95	140.95	
	STD	2.55	3.11	2.50	2.73	2.44	2.54	3.20	2.50	2.72	2.72	
	Min	134.46	124.89	134.00	134.00	134.00	135.00	131.00	134.00	136.00	136.00	
	Max	146.00	144.75	146.00	151.56	148.50	146.00	151.56	149.00	146.00	146.00	
	Median	140.71	140.00	140.00	141.00	141.00	141.00	141.00	140.44	141.00	141.00	
	Median diff.		-1.00	-1.00		0.00	0.00		0.00	0.00	0.00	
	P value		0.0534	0.0711		0.3120	0.5510		0.1699	0.9970	0.9970	
CL-	Evaluated	81	75	63	85	79	67	86	81	73	73	
	Mean	102.20	101.25	101.76	102.51	102.83	102.76	102.32	102.16	102.60	102.60	
	STD	2.51	2.79	2.75	3.22	2.80	2.61	3.52	2.50	2.65	2.65	
	Min	94.00	95.09	91.60	90.67	94.36	98.00	88.55	92.91	91.45	91.45	
	Max	107.78	107.76	108.67	109.64	108.40	109.20	110.00	108.67	109.20	109.20	
	Median	102.00	101.20	101.64	102.57	102.80	102.36	102.80	102.00	102.80	102.80	
	Median diff.		-0.89	-0.73		0.00	0.00		-0.73	0.00	0.00	
	P value		0.0032	0.0571		0.6694	0.4484		0.3096	0.7246	0.7246	
K+	Evaluated	91	82	74	95	88	76	95	88	82	82	
	Mean	4.11	4.17	4.22	4.35	4.20	4.24	4.19	4.31	4.25	4.25	
	STD	0.51	0.53	0.55	0.72	0.52	0.59	0.51	0.59	0.72	0.72	
	Min	2.52	2.70	2.96	3.26	2.86	2.54	3.18	3.05	2.28	2.28	
	Max	5.58	5.31	6.66	8.36	5.63	6.46	5.90	6.70	7.85	7.85	

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS R8D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 65
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Imipramine						Placebo						Reboxetine					
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment		
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
K+																		
	Median	4.11	4.14	4.20	4.25	4.25	4.25	4.25	4.25	4.25	4.25	4.14	4.23	4.16				
	Median diff.		0.02	0.08			-0.10	-0.11					0.09	0.03				
	P value		0.6763	0.1237			0.0875	0.1038					0.0750	0.7753				
Ca++	Evaluated	83	75	67	89	86	73	87	83	78								
	Mean	4.93	4.92	4.87	4.96	4.90	4.96	4.95	4.98	4.89								
	STD	0.27	0.38	0.39	0.29	0.32	0.32	0.30	0.32	0.30								
	Min	4.10	3.70	3.65	4.25	3.70	4.25	3.85	4.00	4.10								
	Max	5.45	5.62	5.55	5.54	5.74	5.66	5.60	5.88	5.60								
	Median	4.96	4.99	4.93	5.00	4.90	4.92	5.00	5.00	4.92								
	Median diff.		0.00	-0.04		-0.06	-0.04		0.00	-0.05								
	P value		0.9538	0.4169		0.0380	0.4648		0.7097	0.1684								
PO4--	Evaluated	76	69	64	89	85	73	86	81	73								
	Mean	1.24	1.30	1.26	1.33	1.27	1.31	1.25	1.26	1.26								
	STD	0.16	0.26	0.16	0.41	0.21	0.18	0.19	0.17	0.35								
	Min	0.62	0.79	0.77	0.86	0.85	0.88	0.86	0.67	0.65								
	Max	1.63	2.54	1.67	4.84	2.42	1.92	1.89	1.74	3.90								
	Median	1.24	1.29	1.26	1.28	1.26	1.28	1.23	1.26	1.21								
	Median diff.		0.05	0.02		-0.03	-0.02		0.02	0.00								
	P value		0.1199	0.1554		0.1199	0.7076		0.1579	0.4300								

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/015
TABLE No.: 66

URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS ACCORDING TO TIME INTERVAL, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Reboxetine

	Days of treatment																		
	Screening						1-21 days						22-42 days						
	Female		Male		Total		Female		Male		Total		Female		Male		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
SPECIFIC GRAVITY	Normal	30	100.0	19	100.0	49	100.0	29	96.7	19	100.0	48	98.0	23	95.8	17	94.4	40	95.2
	Not done							1	3.3			1	2.0	1	4.2	1	5.6	2	4.8
	Total	30	100.0	19	100.0	49	100.0	30	100.0	19	100.0	49	100.0	24	100.0	18	100.0	42	100.0
ALBUMIN	Absent	43	93.5	34	100.0	77	96.3	41	91.1	32	94.1	73	92.4	33	84.6	31	93.9	64	88.9
	Present	3	6.5			3	3.8	2	4.4	2	5.9	4	5.1	5	12.8	2	6.1	7	9.7
	Not done							2	4.4			2	2.5	1	2.6			1	1.4
SUGAR	Total	46	100.0	34	100.0	80	100.0	45	100.0	34	100.0	79	100.0	39	100.0	33	100.0	72	100.0
	Absent	48	98.0	33	97.1	81	97.6	46	95.8	33	97.1	79	96.3	40	97.6	32	97.0	72	97.3
	Present	1	2.0	1	2.9	2	2.4			1	2.9	1	1.2			1	3.0	1	1.4
RBC	Not done							2	4.2			2	2.4	1	2.4			1	1.4
	Total	49	100.0	34	100.0	83	100.0	48	100.0	34	100.0	82	100.0	41	100.0	33	100.0	74	100.0
	Absent	32	65.3	20	58.8	52	62.3	34	70.8	23	67.6	57	69.5	25	61.0	22	66.7	48	64.9
RBC	Present	14	28.7	8	23.5	22	26.7	10	20.8	4	11.8	14	17.1	11	26.9	5	14.9	16	21.6
	Not done							1	2.0	1	2.9	2	2.4	1	2.4			1	1.4
	Total	46	100.0	28	100.0	74	100.0	45	100.0	28	100.0	73	100.0	38	100.0	27	100.0	65	100.0
RBC	Absent	26	56.5	11	32.1	37	44.1	24	52.2	15	42.9	39	47.6	18	46.2	15	41.9	33	43.2
	Present	16	34.5	12	35.3	28	33.9	16	34.0	8	22.9	24	29.3	15	38.5	7	18.8	22	29.1
	Not done							1	2.2			1	1.2	1	2.6			1	1.3
RBC	Total	42	100.0	23	100.0	65	100.0	41	100.0	23	100.0	64	100.0	34	100.0	22	100.0	56	100.0

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 66

URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS ACCORDING TO TIME INTERVAL, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Imipramine

	Days of treatment																		
	Screening						1-21 days						22-42 days						
	Female			Male			Total			Female			Male			Total			
	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	
SPECIFIC GRAVITY	Normal	33	100.0	18	100.0	51	100.0	30	90.9	14	82.4	44	88.0	24	100.0	15	88.2	39	95.1
	Not done							3	9.1	3	17.6	6	12.0			2	11.8	2	4.9
	Total	33	100.0	18	100.0	51	100.0	33	100.0	17	100.0	50	100.0	24	100.0	17	100.0	41	100.0
ALBUMIN	Absent	44	91.7	27	93.1	71	92.2	41	85.4	24	85.7	65	85.5	29	78.4	22	84.6	51	81.0
	Present	4	8.3	2	6.9	6	7.8	5	10.4	1	3.6	6	7.9	6	16.2	1	3.8	7	11.1
	Not done							2	4.2	3	10.7	5	6.6	2	5.4	3	11.5	5	7.9
SUGAR	Total	48	100.0	29	100.0	77	100.0	48	100.0	28	100.0	76	100.0	37	100.0	26	100.0	63	100.0
	Absent	47	95.9	29	96.7	76	96.2	47	95.9	26	89.7	73	93.6	36	94.7	23	85.2	59	90.8
	Present	2	4.1	1	3.3	3	3.8									2	7.4	2	3.1
RBC	Not done							2	4.1	3	10.3	5	6.4	2	5.3	2	7.4	4	6.2
	Total	49	100.0	30	100.0	79	100.0	49	100.0	29	100.0	78	100.0	38	100.0	27	100.0	65	100.0
	Absent	36	76.6	21	75.0	57	76.0	32	68.1	16	59.3	48	64.9	24	66.7	17	68.0	41	67.2
HBC	Present	11	23.4	7	25.0	18	24.0	11	23.4	8	29.6	19	25.7	10	27.8	5	20.0	15	24.6
	Not done							4	8.5	3	11.1	7	9.5	2	5.6	3	12.0	5	8.2
	Total	47	100.0	28	100.0	75	100.0	47	100.0	27	100.0	74	100.0	36	100.0	25	100.0	61	100.0
HBC	Absent	24	54.5	16	66.7	40	58.8	22	50.0	11	47.8	33	49.3	19	57.6	13	61.9	32	59.3
	Present	20	45.5	8	33.3	28	41.2	19	43.2	9	39.1	28	41.8	12	36.4	5	23.8	17	31.5
	Not done							3	6.8	3	13.0	6	9.0	2	6.1	3	14.3	5	9.3
Total		44	100.0	24	100.0	68	100.0	44	100.0	23	100.0	67	100.0	33	100.0	21	100.0	54	100.0

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 66

URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS ACCORDING TO TIME INTERVAL, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Placebo

	Days of treatment																		
	Screening						1-21 days						22-42 days						
	Female			Male			Total			Female			Male			Total			
	No.	%	Z	No.	%	Z	No.	%	Z	No.	%	Z	No.	%	Z	No.	%	Z	
SPECIFIC GRAVITY	Normal	30	100.0	25	100.0	55	100.0	29	96.7	21	84.0	50	90.9	24	92.3	18	81.8	42	87.5
	Not done							1	3.3	4	16.0	5	9.1	2	7.7	4	18.2	6	12.5
	Total	30	100.0	25	100.0	55	100.0	30	100.0	25	100.0	55	100.0	26	100.0	22	100.0	48	100.0
ALBUMIN	Absent	35	94.6	39	90.7	74	92.5	35	97.2	36	83.7	71	89.9	31	96.9	31	81.6	62	88.6
	Present	2	5.4	4	9.3	6	7.5	1	2.8	4	9.3	5	6.3			2	5.3	2	2.9
	Not done									3	7.0	3	3.8	1	3.1	5	13.2	6	8.6
SUGAR	Total	37	100.0	43	100.0	80	100.0	36	100.0	43	100.0	79	100.0	32	100.0	38	100.0	70	100.0
	Absent	40	100.0	45	100.0	85	100.0	38	97.4	41	91.1	79	94.0	33	94.3	34	85.0	67	89.3
	Present							1	2.6	1	2.2	2	2.4			1	2.5	1	1.3
RBC	Not done									3	6.7	3	3.6	2	5.7	5	12.5	7	9.3
	Total	40	100.0	45	100.0	85	100.0	39	100.0	45	100.0	84	100.0	35	100.0	40	100.0	75	100.0
	Absent	26	74.3	25	61.0	51	67.1	24	70.6	22	53.7	46	61.3	27	84.4	22	59.5	49	71.0
HBC	Present	9	25.7	16	39.0	25	32.9	7	20.6	15	36.6	22	29.3	5	15.6	11	29.7	16	23.2
	Not done									3	8.8	4	9.8	7	9.3			4	5.8
	Total	35	100.0	41	100.0	76	100.0	34	100.0	41	100.0	75	100.0	32	100.0	37	100.0	69	100.0
HBC	Absent	21	63.6	19	55.9	40	59.7	19	59.4	14	41.2	33	50.0	21	70.0	15	48.4	36	59.0
	Present	12	36.4	15	44.1	27	40.3	10	31.3	16	47.1	26	39.4	9	30.0	11	35.5	20	32.8
	Not done									3	9.4	4	11.8	7	10.6			5	8.2
Total		33	100.0	34	100.0	67	100.0	32	100.0	34	100.0	66	100.0	30	100.0	31	100.0	61	100.0

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PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/015

TABLE No.: 67

URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS AT BASELINE AND LAST ASSESSMENT, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Reboxetine

	Baseline						Last assessment									
	Female			Male			Female			Male			Total			
	No.	%		No.	%		No.	%		No.	%		No.	%		
SPECIFIC GRAVITY	Normal	30	100.0	19	100.0	49	100.0	29	96.7	18	94.7	47	95.9			
	Not done							1	3.3	1	5.3	2	4.1			
	Total	30	100.0	19	100.0	49	100.0	30	100.0	19	100.0	49	100.0			
	Absent	43	93.5	34	100.0	77	96.3	39	84.8	32	94.1	71	88.8			
ALBUMIN	Present	3	6.5			3	3.8	6	13.0	2	5.9	8	10.0			
	Not done							1	2.2			1	1.2			
	Total	46	100.0	34	100.0	80	100.0	46	100.0	34	100.0	80	100.0			
	Absent	48	98.0	33	97.1	81	97.6	48	98.0	32	94.1	80	96.4			
SUGAR	Present	1	2.0	1	2.9	2	2.4					2	2.4			
	Not done									1	2.0		1.2			
	Total	49	100.0	34	100.0	83	100.0	49	100.0	34	100.0	83	100.0			
	Absent	32	69.6	20	71.4	52	70.3	31	67.4	22	78.6	53	71.6			
RBC	Present	14	30.4	8	28.6	22	29.7	14	30.4	6	21.4	20	27.0			
	Not done									1	2.2		1.4			
	Total	46	100.0	28	100.0	74	100.0	46	100.0	28	100.0	74	100.0			
	Absent	26	61.9	11	47.8	37	56.9	21	50.0	15	65.2	36	55.4			
HBC	Present	16	38.1	12	52.2	28	43.1	20	47.6	8	34.8	28	43.1			
	Not done									1	2.4		1.5			
	Total	42	100.0	23	100.0	65	100.0	42	100.0	23	100.0	65	100.0			
	Absent															

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 67
URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS AT BASELINE AND LAST ASSESSMENT, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Imipranizine

	Urinalysis	Baseline						Last assessment								
		Female			Male			Female			Male			Total		
		No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%
SPECIFIC GRAVITY	Normal	33	100.0	18	100.0	51	100.0	33	100.0	16	88.9	49	96.1			
	Not done													2	11.1	2
	Total	33	100.0	18	100.0	51	100.0	33	100.0	18	100.0	51	100.0			
ALBUMIN	Absent	44	91.7	27	93.1	71	92.2	39	81.3	25	66.2	64	83.1			
	Present	4	8.3	2	6.9	6	7.8	7	14.6	1	3.4	8	10.4			
	Not done													2	4.2	3
SUGAR	Total	48	100.0	29	100.0	77	100.0	48	100.0	29	100.0	77	100.0			
	Absent	47	95.9	29	96.7	76	96.2	47	95.9	26	86.7	73	92.4			
	Present	2	4.1	1	3.3	3	3.8					2	2.5			
RBC	Total	49	100.0	30	100.0	79	100.0	49	100.0	30	100.0	79	100.0			
	Absent	36	76.6	21	75.0	57	76.0	31	66.0	18	64.3	49	65.3			
	Present	11	23.4	7	25.0	18	24.0	14	29.8	7	25.0	21	28.0			
HBC	Total	47	100.0	28	100.0	75	100.0	47	100.0	28	100.0	75	100.0			
	Absent	24	54.5	16	66.7	40	58.8	22	50.0	14	58.3	36	52.9			
	Present	20	45.5	8	33.3	28	41.2	20	45.5	7	29.2	27	39.7			
Total	Not done													2	4.5	3
	Total	44	100.0	24	100.0	68	100.0	44	100.0	24	100.0	68	100.0			

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PHARMACIA CNS R&D
 REBOXYTINE - PROTOCOL 20124/015
 TABLE No.: 67
 URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS AT BASELINE AND LAST ASSESSMENT, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Placebo

	Baseline						Last assessment						
	Female		Male		Total		Female		Male		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
Urinalysis													
SPECIFIC GRAVITY	Normal	30	100.0	25	100.0	55	100.0	28	93.3	21	84.0	49	89.1
	Not done							2	6.7	4	16.0	6	10.9
	Total	30	100.0	25	100.0	55	100.0	30	100.0	25	100.0	55	100.0
ALBUMIN	Absent	35	94.6	39	90.7	74	92.5	35	94.6	36	83.7	71	88.8
	Present	2	5.4	4	9.3	6	7.5	1	2.7	2	4.7	3	3.8
	Not done							1	2.7	5	11.6	6	7.5
SUGAR	Total	37	100.0	43	100.0	80	100.0	37	100.0	43	100.0	80	100.0
	Absent	40	100.0	45	100.0	85	100.0	37	92.5	39	86.7	76	89.4
	Present							1	2.5	1	2.2	2	2.4
RBC	Total	40	100.0	45	100.0	85	100.0	40	100.0	45	100.0	85	100.0
	Absent	26	74.3	25	61.0	51	67.1	30	85.7	24	58.5	54	71.1
	Present	9	25.7	16	39.0	25	32.9	5	14.3	13	31.7	18	23.7
RBC	Total	35	100.0	41	100.0	76	100.0	35	100.0	41	100.0	76	100.0
	Absent	21	63.6	19	55.9	40	59.7	23	69.7	16	47.1	39	58.2
	Present	12	36.4	15	44.1	27	40.3	10	30.3	13	38.2	23	34.3
Total	Not done												
	Total	33	100.0	34	100.0	67	100.0	33	100.0	34	100.0	67	100.0

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 66

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Urinalysis test at baseline	Days of treatment									
	1-21 days					22-42 days				
	Absent	Present	Not done	Total	Total	Absent	Present	Not done	Total	
ALBUMIN	Absent	72	3	1	76	64	4	1	69	
	Present	1	1	1	3		3		3	
	Total	73	4	2	79	64	7	1	72	
SUGAR	Absent	78		2	80	71	1	1	73	
	Present	1	1		2	1			1	
	Total	79	1	2	82	72	1	1	74	
RBC	Absent	46	3	2	51	41	6	1	48	
	Present	11	11		22	7	10		17	
	Total	57	14	2	73	48	16	1	65	
WBC	Absent	34	1	1	36	28	4	1	33	
	Present	5	23		28	5	18		23	
	Total	39	24	1	64	33	22	1	56	

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PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20124/015
TABLE No. : 68

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Imipramine

Urinalysis test at baseline	Days of treatment									
	1-21 days					22-42 days				
	Absent	Present	Not done	Total	Absent	Present	Not done	Total		
ALBUMIN	Absent	61	4	5	70	50	5	4	59	
	Present	4	2		6	1	2	1	4	
	Total	65	6	5	76	51	7	5	63	
SUGAR	Absent	71		4	75	57	1	4	62	
	Present	2		1	3	2	1		3	
	Total	73		5	78	59	2	4	65	
RBC	Absent	44	7	5	56	38	7	3	48	
	Present	4	12	2	18	3	8	2	13	
	Total	48	19	7	74	41	15	5	61	
WBC	Absent	28	7	4	39	29	4	2	35	
	Present	5	21	2	28	3	13	3	19	
	Total	33	28	6	67	32	17	5	54	

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PHARMACIA CNS R&D

REBOXYTINE - PROTOCOL 20124/015
TABLE No.: 68

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Placebo

Urinalysis test at baseline	Days of treatment									
	1-21 days					22-42 days				
	Absent	Present	Not done	Total	Absent	Present	Not done	Total		
ALBUMIN	Absent	69	2	2	73	60		6	66	
	Present	2	3	1	6	2	2		4	
	Total	71	5	3	79	62	2	6	70	
SUGAR	Absent	79	2	3	84	67	1	7	75	
	Total	79	2	3	84	67	1	7	75	
	Absent	42	4	4	50	43	3	2	48	
RBC	Present	4	18	3	25	6	13	2	21	
	Total	46	22	7	75	49	16	4	69	
	Absent	30	5	4	39	32	4	2	38	
WBC	Present	3	21	3	27	4	16	3	23	
	Total	33	26	7	66	36	20	5	61	

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 69

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Urinalysis test at baseline	Total						Last assessment					
	1-21 days			22-42 days			1-21 days			22-42 days		
	Absent	Present	Not done	Total	Absent	Present	Not done	Total	Absent	Present	Not done	Total
ALBUMIN	Absent	71	5	1	77	7	1	8	64	4	1	69
	Present		3	3						3		3
	Total	71	8	1	80	7	1	8	64	7	1	72
SUGAR	Absent	79	1	1	81	8		8	71	1		73
	Present	1	1		2		1	1				1
	Total	80	2	1	83	8	1	9	72	1		74
RBC	Absent	45	6	1	52	4		4	41	6		48
	Present	8	14		22	1	4	5	7	10		17
	Total	53	20	1	74	5	4	9	48	16	1	65
WBC	Absent	31	5	1	37	3		4	28	4		33
	Present	5	23		28		5	5	5	18		23
	Total	36	28	1	65	3	6	9	33	22	1	56

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REBOXYLINE - PROTOCOL 20124/015
TABLE No.: 69

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Indipramine

Urinalysis test at baseline	Total						Last assessment						
	1-21 days			22-42 days			1-21 days			22-42 days			
	Absent	Present	Not done	Total	Absent	Present	Not done	Total	Absent	Present	Not done	Total	
ALBUMIN	Absent	62	5	4	71	12			12	50	5	4	59
	Present	2	3	1	6	1	1		2	1	2	1	4
	Total	64	8	5	77	13	1		14	51	7	5	63
SUGAR	Absent	71	1	4	76	14			14	57	1	4	62
	Present	2	1		3					2	1		3
	Total	73	2	4	79	14			14	59	2	4	65
RBC	Absent	46	8	3	57	8	1		9	38	7	3	48
	Present	3	13	2	18		5		5	3	8	2	13
	Total	49	21	5	75	8	6		14	41	15	5	61
MBC	Absent	33	5	2	40	4			4	29	4	2	35
	Present	3	22	3	28		9		9	3	13	3	19
	Total	36	27	5	68	4	10		14	32	17	5	54

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REBORNETINE - PROTOCOL 20124/015
TABLE No. : 69

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Placebo

Urinalysis test at baseline	Total						Last assessment						
	Total			1-21 days			22-42 days			Total			
	Absent	Present	Not done	Absent	Present	Total	Absent	Present	Not done	Absent	Present	Not done	Total
ALBUMIN	Absent	68	6	74	8	60	6	66					
	Present	3	3	6	1	2	2	4					
	Total	71	9	80	9	62	8	70					
SUGAR	Absent	76	2	78	9	67	1	75					
	Total	76	2	78	9	67	1	75					
	Absent	46	3	49	3	43	3	48					
REC	Present	8	15	23	2	13	2	21					
	Total	54	18	72	5	49	4	69					
	Absent	34	4	38	2	32	4	38					
MEC	Present	5	19	24	1	16	3	23					
	Total	39	23	62	3	36	5	41					
	Absent	34	4	38	2	32	4	38					

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 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 70

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Reboxetine

Urinalysis test at baseline	Days of treatment					
	1-21 days			22-42 days		
	Normal	Not done	Total	Normal	Not done	Total
SPECIFIC GRAVITY Normal	48	1	49	40	2	42
Total	48	1	49	40	2	42

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 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 70

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Imipramine

Urinalysis test at baseline	Days of treatment					
	1-21 days			22-42 days		
	Normal	Not done	Total	Normal	Not done	Total
SPECIFIC GRAVITY	44	6	50	39	2	41
Total	44	6	50	39	2	41

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 REBOMETINE - PROTOCOL 20124/015
 TABLE No. : 70

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Placebo

Urinalysis test at baseline	Days of treatment					
	1-21 days			22-42 days		
	Normal	Not done	Total	Normal	Not done	Total
SPECIFIC GRAVITY	50	5	55	42	6	48
Total	50	5	55	42	6	48

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 71

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Reboxetine

Urinalysis test at baseline	Total			Last assessment				
	Normal	Not done	Total	1-21 days		22-42 days		
				Normal	Total	Normal	Not done	Total
SPECIFIC GRAVITY	47	2	49	7	7	40	2	42
Total	47	2	49	7	7	40	2	42

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REBOMETINE - PROTOCOL 20124/015

TABLE No.: 71

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Imipramine

Urinalysis test at baseline	Total			Last assessment				
	Normal	Not done	Total	1-21 days		22-42 days		
				Normal	Total	Normal	Not done	Total
SPECIFIC GRAVITY Normal	49	2	51	10	10	39	2	41
Total	49	2	51	10	10	39	2	41

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RESOMETINE - PROTOCOL 20124/015

TABLE No.: 71

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Placebo

Urinalysis test at baseline	Total			Last assessment					
	Normal	Not done	Total	1-21 days		22-42 days		Total	
				Normal	Total	Normal	Not done		
SPECIFIC GRAVITY	49	6	55	7	7	42	6	48	
Total	49	6	55	7	7	42	6	48	

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 72

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY - SHIFT TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																					
	Imipramine									Reboxetine												
	Days of treatment						Days of treatment			Days of treatment			Days of treatment			Days of treatment						
	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42				
HB	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val		
	3	3			4	2											6	4	4	3		
									1	89				4	74	1		1	72	1	66	2
HT	Low	8	3		7	4			1	1.000												
RBC	Low	10	4		7	6			2	2												
PLATELETS	Low	2			3				1													

P val : probability from Maxwell's test

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 72

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY - SHIFT TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																			
	Imipramine									Placebo										
	1-21			22-42			1-21			22-42			1-21			22-42				
	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
HBC	LOW	4	3		4	3			2	2			2	2			6			
	NORMAL	1	66	3	4	56	2		2	80	2		1	69	4		73	3		2
	HIGH				1	0.135		1	0.343	3	1	0.905	2	3	0.435	3	2	0.050	4	2
HBC: N	LOW	5	2	1	6	2			6	3			4	2			6	6		5
	NORMAL	1	51	5	1	50	4		3	61	7		3	60	5		51	5		2
	HIGH		3	3	0.424	2	2	0.607	5	0.846	3	1	0.705	3	1	0.705	5	3	0.607	5
HBC: E	LOW	3	1	1	1	3	1		5	1	1		6	2			3	8		6
	NORMAL	10	51	2	3	51	2		6	60	3		5	52	4		1	57	5	2
	HIGH		1	2	0.009	1	3	0.595	5	3	0.363	3	5	0.490	2	1	0.055	2	1	0.139
HBC: B	LOW								1				1				2			2
	NORMAL	2	60	2		58	3		1	75	3		69	3			70	3		72
	HIGH		1	2	0.223	1	1	0.368	2	0.549	2		0.250							0.082
HBC: L	LOW	8	4		4	5			3	4			2	4			4	6		6
	NORMAL	3	43	2	6	37	4		3	65	5		4	58	5		3	50	6	2
	HIGH		1	7	0.162	7	7	0.635	5	6	0.931	4	4	0.946	4	4	0.946	10	3	0.368
HBC: K	LOW	5	11		7	4			2	8			2	6			2	10		6
	NORMAL	3	49	1	5	47	2		5	63	3		5	56	3		3	56	3	5
	HIGH		3	3	0.062	1	1	0.815	8	2	0.227	1	4	0.777	1	4	1	0.158	4	2

P val : probability from Maxwell's test

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PHARMACIA CNS R&D

REBOSETINE - PROTOCOL 20124/015
TABLE No.: 72

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY - SHIFT TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																			
	Imipramine									Reboxetine										
	1-21			22-42			1-21			22-42			1-21			22-42				
	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val		
SGOT	LOW	1		1			1													
	NORMAL	70	3	62	6		79	1	1	65	2		79	1		69	5			
	HIGH	5	1	0.472	3	2	0.508	4	3	0.247	6	2	0.223	6	1	0.102	8	1	0.429	
SGPT	LOW	1	3		5										1	3		1	3	
	NORMAL	1	62	4	49	9		2	68	4		2	58	2		69		63	3	
	HIGH	2	2	0.435	2	3	0.009	5	2	0.348	5	2	0.193	6	3	0.045	6	3	0.135	
GAMMA GT	LOW	2			1															
	NORMAL	1	54	3	43	5		71	3		55	2		2	65	1		60	4	
	HIGH	1	3	11	0.368	2	11	0.319	7	7	0.344	5	10	0.453	5	9	0.097	7	5	0.549
LDH	LOW	6	3		4	1		10	4		8	4		10	1		5	3		
	NORMAL	3	47	6	40	4		5	49	3		2	42	2		51	3		47	6
	HIGH	1	2	0.168	1	1	0.249	5	0.211	3	3	0.648	2	4	0.905	2	4	0.905	1	6
ALK. PHOSPH.	LOW	3	2		1	4		2	5		1	4		4	3		3	4		
	NORMAL	2	64	2	56	4		1	74	2		3	63		2	68	3		65	2
	HIGH	1	5	0.846	1	5	0.291	2	5	0.264	2	4	0.343	3	4	0.905	3	4	0.842	

P val : probability from Maxwell's test

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 72

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY - SHIFT TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																							
	Imipramine									Placebo														
	Days of treatment						1-21			22-42			Days of treatment						1-21			22-42		
	Low	Nor.	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val		
GLOBULINS ALPHA 1	2	1			1	3				1	3					2				4	1	2		
	1	47	3		2	37	2	58	1	46	3									48	3	1	50	
		4	1	0.931		3	1	0.819		2	0.766									3		0.082	2	1
GLOBULINS ALPHA 2	2	1			2	3				2						1				2		1	2	
	2	42	2		1	30	6	54	3	45	2					1	45	2		2	47	3	43	
		6	4	0.311		3	4	0.368		3	2	0.905				4	1	0.717		3	2	1.000	1	2
GLOBULINS BETA	4	40	6		4	33	4	45	5							2				2		3	1	
		4	5	0.111		3	5	0.126		5	7	0.846				4	1	0.193		1	4	4	1.000	
		3	5		1	3		7	5		8	5				3	31			3	6		3	
GLOBULINS GAMMA	1	44	3		1	42	1	44	4							3	31			4	38	2	4	
		1	2	0.160		1	0.607		1	4	0.214					1	3	0.472		1	4	1	0.479	
		1	2	0.160		1	0.607		1	4	0.214					1	3	0.472		1	4	1	0.479	

P val : probability from Maxwell's test

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 72

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY - SHIFT TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																										
	Imipramine									Placebo									Reboxetine								
	Days of treatment									Days of treatment									Days of treatment								
	1-21			22-42			1-21			22-42			1-21			22-42			1-21			22-42					
Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val				
TOT. CHOLEST.	1	1	1		3			2	1			2	1			2				1	1						
	1	41	9		1	36	7		2	46	4		2	38	2		2	46	5		4	46	1				
		6	18	0.551	6	15	0.584		12	20	0.115		10	19	0.059		12	17	0.087		10	14	0.007				
TRIGLYCERIDES	2				1				1											2	2						
	1	49	8		1	45	3		4	52	11		3	47	7		3	51	6		2	46	6				
		5	12	0.599	6	10	0.607		3	15	0.056		5	10	0.189		1	9	0.469		9	9	0.670				
GLUCOSE	1	3			2				2											4							
	1	66	2		2	52	5		3	75	6		4	62	5		7	60	6		2	57	7				
		1	5	0.292	7	3	0.846		2	2	0.333		2	2	0.214		2	4	0.576		4	7	0.476				

P val : probability from Maxwell's test

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PHARMACIA CNS R2D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 72

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY - SHIFT TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																										
	Inipixamine									Placebo									Reboxetine								
	Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment			Days of treatment					
	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42									
MA+	LOW	2	1		1																						
	NORMAL	4	76	2	70	3	80	1	2	72	1	79	1	76													
	HIGH		0.688		1.000	4	0.247		3	0.082	2	0.142		3	0.018												
CL-	LOW	1	2	1		1	4	1		5		1	5		1	4											
	NORMAL	7	57	1	57	2	55	10	6	51	6	64	1	56	2												
	HIGH	3	0.226	3	0.135	4	2	0.123	4	0.067	6	0.014	5	4	0.214												
K+	LOW	2	3	2	3	2			3			1	4		1	4											
	NORMAL	3	66	5	62	4	75	4	2	66	1	71	6	65	5												
	HIGH	3	0.779	2	0.819	3	0.126		2	0.311	2	0.156	1	2	0.264												
Ca++	LOW	2		3		3			2		2		2		3												
	NORMAL	9	62	2	57	6	75	1	3	64	1	75	3	69	1												
	HIGH		0.004		0.030	1	0.607		1	0.905	1	0.223	1	0.905													
PO4--	LOW	2		2	1	1	2		1	2		3	1	2													
	NORMAL	3	58	3	56	3	68	3	59	4	67	3	58	3													
	HIGH	1	0.135	1	0.368	8	10.321		5	2	0.368	3	1	0.882	6	1	0.549										

P val : probability from Maxwell's test

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PHARMACIA CMS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 73

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Serocon	Days of treatment					
		1-21		22-42			
		No	%	No	%	No	%
HT	Placebo	89	100.0	84	100.0	72	100.0
	down					1	1.4
	Reboxetine	83	100.0	78	100.0	70	100.0
	down	1	1.2				
RBC	Imipramine	87	100.0	77	100.0	70	100.0
	down	1	1.1				
	Placebo	98	100.0	93	100.0	81	100.0
	down					1	1.2
Reboxetine	Eval.	93	100.0	87	100.0	80	100.0
	down	2	2.2	1	1.1		
	Imipramine	83	100.0	73	100.0	67	100.0
	down	1	1.2				
PLATELETS	Placebo	98	100.0	89	100.0	74	100.0
	down	1	1.1	1	1.1	1	1.4
	Reboxetine	88	100.0	79	100.0	75	100.0
	down	1	1.1			2	2.7
MBC	Imipramine	87	100.0	78	100.0	71	100.0
	down	1	1.1	1	1.3	1	1.4
	up					1	1.4
	Placebo	98	100.0	93	100.0	81	100.0
Reboxetine	up	2	2.0	1	1.1		
	Eval.	93	100.0	87	100.0	80	100.0
	down	1	1.1			1	1.2

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No. : 73

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Days of treatment									
	Screen			1-21			22-42			
	No	Z	X	No	Z	X	No	Z	X	
HBC: N	Roboxetine	up				2	2.3			
	Imipramine	Eval.	81	100.0	71	100.0	68	100.0		
		down	1	1.2						
	Placebo	Eval.	93	100.0	86	100.0	78	100.0		
		down	1	1.1	1	1.2	1	1.3		
	Roboxetine	Eval.	88	100.0	79	100.0	79	100.0		
		down	2	2.3						
		up	1	1.1	1	1.3	1	1.3		
		Eval.	80	100.0	70	100.0	66	100.0		
		up	2	2.5	5	7.1	5	7.6		
HBC: E	Imipramine	Eval.	92	100.0	85	100.0	77	100.0		
	Placebo	up	7	7.6	3	3.5	6	7.8		
	Roboxetine	Eval.	87	100.0	77	100.0	78	100.0		
		up	3	3.4	4	5.2	5	6.4		
	Imipramine	Eval.	78	100.0	67	100.0	65	100.0		
		up	1	1.3	1	1.5	2	3.1		
	Placebo	Eval.	90	100.0	83	100.0	73	100.0		
		up	1	1.1	1	1.2	3	4.1		
	Roboxetine	Eval.	86	100.0	77	100.0	77	100.0		
		up			3	3.9	2	2.6		
HBC: L	Imipramine	Eval.	87	100.0	76	100.0	71	100.0		
		down	1	1.1	6	7.9	2	2.8		
		up	2	2.3	2	2.6	2	2.8		
		up								

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 73
LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Screen	Days of treatment					
		1-21		22-42			
		No	%	No	%	No	%
MBC: L	Placebo	98	100.0	92	100.0	81	100.0
	Eval.						
	down	1	1.0	2	2.2	1	1.2
	up	2	2.0	2	2.2	2	2.5
MBC: M	Reboxetine	91	100.0	82	100.0	79	100.0
	Eval.						
	down	4	4.4	2	2.4	4	5.1
	up	4	4.4	1	1.2	2	2.5
CREATININE	Imipramine	87	100.0	75	100.0	71	100.0
	Eval.						
	up	4	4.6	1	1.3	2	2.8
	down	98	100.0	92	100.0	81	100.0
BUN	Placebo	98	100.0	92	100.0	81	100.0
	Eval.						
	up	4	4.1			1	1.2
	down	91	100.0	81	100.0	79	100.0
URIC ACID	Reboxetine	92	100.0	84	100.0	76	100.0
	Eval.						
	up			1	1.2		
	down	35	100.0	35	100.0	29	100.0
LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE	Placebo	1	2.9				
	Eval.						
	up	37	100.0	36	100.0	29	100.0
	down					1	3.4
LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE	Imipramine	80	100.0	72	100.0	66	100.0
	Eval.						
	up	1	1.2	1	1.4	2	3.0
	down	90	100.0	85	100.0	76	100.0
LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE	Placebo						
	Eval.						
	up			2	2.4	1	1.3
	down	86	100.0	79	100.0	79	100.0

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 73

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Days of treatment											
	Screen			1-21			22-42					
	No	Z	%	No	Z	%	No	Z	%			
URIC ACID	Reboxetine	up		2	2.5	1	1.3					
	Placebo	Eval.	93	100.0	88	100.0	73	100.0				
ALBUMINE	Reboxetine	up				1	1.4					
	Placebo	Eval.	93	100.0	89	100.0	82	100.0				
TOT BILIRUBIN	Reboxetine	up		1	1.1							
DIR BILIRUBIN	Reboxetine	up		38	100.0	31	100.0					
	Placebo	Eval.	39	100.0	38	100.0	31	100.0				
SGOT	Reboxetine	up	1	2.6	1	2.6	1	3.2				
	Placebo	Eval.	39	100.0	36	100.0	31	100.0				
SGPT	Reboxetine	up	1	2.6								
	Placebo	Eval.	90	100.0	80	100.0	75	100.0				
GAMMA GT	Reboxetine	up	2	2.2	1	1.2	3	4.0				
	Placebo	Eval.	95	100.0	88	100.0	76	100.0				
ALBUMINE	Reboxetine	up	2	2.1								
	Placebo	Eval.	94	100.0	88	100.0	84	100.0				
SGPT	Reboxetine	up	2	2.1			1	1.2				
	Placebo	Eval.	84	100.0	75	100.0	69	100.0				
ALBUMINE	Reboxetine	up	2	2.4	3	4.0	2	2.9				
	Placebo	Eval.	88	100.0	81	100.0	69	100.0				
GAMMA GT	Reboxetine	up	2	2.3	3	3.7	1	1.4				
	Placebo	Eval.	89	100.0	84	100.0	79	100.0				
ALBUMINE	Reboxetine	up	1	1.1			1	1.3				
	Placebo	Eval.	82	100.0	75	100.0	62	100.0				
SGPT	Reboxetine	up	9	11.0	6	8.0	9	11.5				
	Placebo	Eval.	73	100.0	66	100.0	57	100.0				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 73

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Days of treatment											
	Screen		1-21				22-42					
	No	%	No	%	No	%	No	%	No	%		
GAMMA GT	Placebo	Eval. up	95	100.0	88	100.0	72	100.0				
	Reboxetine	Eval. up	4	4.2	2	2.3						
LDH	Placebo	Eval. up	88	100.0	82	100.0	76	100.0				
	Placebo	Eval. up	5	5.7	3	3.7	3	3.9				
ALK. PHOSPH.	Placebo	Eval. up	82	100.0	76	100.0	64	100.0				
	Imipramine	Eval. up	1	1.2								
GLOBULINS ALPHA 1	Placebo	Eval. up	88	100.0	79	100.0	74	100.0				
	Imipramine	Eval. up							1	1.4		
GLOBULINS ALPHA 2	Placebo	Eval. down	97	100.0	91	100.0	77	100.0				
	Imipramine	Eval. down	1	1.0	1	1.1	1	1.3				
GLOBULINS ALPHA 1	Placebo	Eval. up	67	100.0	59	100.0	49	100.0				
	Imipramine	Eval. up			1	1.7						
GLOBULINS ALPHA 2	Placebo	Eval. down	71	100.0	67	100.0	54	100.0				
	Imipramine	Eval. down	3	4.2								
GLOBULINS ALPHA 1	Placebo	Eval. up	2	2.8								
	Reboxetine	Eval. down	67	100.0	59	100.0	60	100.0				
GLOBULINS ALPHA 2	Placebo	Eval. up	1	1.5					1	1.7		
	Imipramine	Eval. up	67	100.0	59	100.0	49	100.0				
GLOBULINS ALPHA 1	Placebo	Eval. up			1	1.7						
	Reboxetine	Eval. up	71	100.0	67	100.0	54	100.0				
GLOBULINS ALPHA 2	Placebo	Eval. up			1	1.5			1	1.9		
	Reboxetine	Eval. up	67	100.0	59	100.0	60	100.0				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012/4/015
TABLE No.: 73
LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Days of treatment											
	Screen			1-21			22-42					
	No	Z	%	No	Z	%	No	Z	%			
GLOBULINS ALPHA 2	up	1	1.5	1	1.7	2	3.3					
	Eval.	67	100.0	59	100.0	49	100.0					
	up	1	1.5	1	1.7							
GLOBULINS BETA	Eval.	71	100.0	67	100.0	54	100.0					
	up			1	1.5							
	Eval.	67	100.0	59	100.0	60	100.0					
GLOBULINS GAMMA	up	2	3.0	2	3.4							
	Eval.	67	100.0	59	100.0	49	100.0					
	down					1	2.0					
TOT. CHOLEST.	Eval.	74	100.0	67	100.0	54	100.0					
	up			1	1.5	1	1.9					
	Eval.	67	100.0	59	100.0	60	100.0					
TRIGLYCERIDES	up	1	1.5			1	1.7					
	Eval.	87	100.0	78	100.0	69	100.0					
	up	7	8.0	7	9.0	6	8.7					
GLOBULINS ALPHA 1	Eval.	94	100.0	87	100.0	74	100.0					
	up	6	6.4	2	2.3	2	2.7					
	Eval.	90	100.0	84	100.0	78	100.0					
GLOBULINS BETA	up	7	7.8	4	4.8	4	5.1					
	Eval.	86	100.0	77	100.0	67	100.0					
	up	10	11.6	9	11.7	4	6.0					
GLOBULINS GAMMA	Eval.	93	100.0	87	100.0	72	100.0					
	up	11	11.8	15	17.2	8	11.1					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 73
 LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Days of treatment											
	Screen			1-21			22-42					
	No	Z	%	No	Z	%	No	Z	%			
TRIGLYCERIDES	Reboxetine	Eval.	89	100.0	83	100.0	77	100.0				
		up	9	10.1	10	12.0	9	11.7				
	Imipramine	Eval.	90	100.0	81	100.0	74	100.0				
GLUCOSE		up	1	1.1								
	Placebo	Eval.	97	100.0	90	100.0	77	100.0				
		up	1	1.1	1	1.1	1	1.3				
Reboxetine		Eval.	95	100.0	89	100.0	81	100.0				
		up	2	2.1	3	3.4	2	2.5				
	Placebo	Eval.	85	100.0	79	100.0	67	100.0				
Cl-		down	1	1.2								
	Reboxetine	Eval.	86	100.0	81	100.0	73	100.0				
		down	1	1.2								
K+	Imipramine	Eval.	91	100.0	82	100.0	75	100.0				
		down	1	1.1	1	1.2	1	1.3				
		up										
Placebo		Eval.	95	100.0	88	100.0	76	100.0				
		down			1	1.1	1	1.3				
		up	3	3.2			2	2.6				
Reboxetine		Eval.	95	100.0	88	100.0	82	100.0				
		down					1	1.2				
		up			1	1.1	1	1.2				
PO4--	Imipramine	Eval.	76	100.0	69	100.0	65	100.0				
		down	1	1.3	3	4.3						

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 73

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Days of treatment									
	Screen			1-21			22-42			
	No	%	Z	No	%	Z	No	%	Z	
P04--	up									
	Imipramine			3	4.3	1	1.5			
	Placebo	89	100.0	85	100.0	73	100.0			
	down	1	1.1	1	1.2	1	1.4			
	up	3	3.4	2	2.4	3	4.1			
	Reboxetine	86	100.0	81	100.0	73	100.0			
down	1	1.2	2	2.5	1	1.4				
up	4	4.7	2	2.5	2	2.7				

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 74

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Vital signs	LIVING														STANDING													
	time interval							time interval							time interval							time interval						
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
S.B.P.	Evaluated	111	111	105	98	96	90	87	111	111	105	98	96	87	111	111	105	98	96	89	87	111	111	105	98	96	89	87
	Mean	126.5	125.2	126.9	125.3	125.7	125.5	126.7	123.9	121.9	122.9	121.7	122.4	121.5	123.9	121.9	122.9	121.7	122.4	122.9	121.5	123.9	121.9	122.9	121.7	122.4	122.9	121.5
	STD	14.5	14.3	14.2	13.8	13.4	13.0	13.5	14.4	16.6	17.1	14.5	14.6	15.2	14.4	16.6	17.1	14.5	14.6	15.2	15.2	14.4	16.6	17.1	14.5	14.6	15.2	15.2
	Median	125.0	125.0	130.0	125.0	125.0	125.0	125.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0
	Min	95.0	95.0	98.0	100.0	90.0	100.0	95.0	90.0	70.0	70.0	85.0	90.0	80.0	90.0	70.0	70.0	85.0	90.0	80.0	80.0	90.0	70.0	70.0	85.0	90.0	80.0	80.0
D.B.P.	Evaluated	111	111	105	98	96	90	87	111	111	105	97	96	87	111	111	105	97	96	89	87	111	111	105	97	96	89	87
	Mean	79.1	77.9	78.0	77.0	78.8	79.2	78.9	78.1	77.1	77.2	76.8	78.7	77.4	78.1	77.1	77.2	76.8	78.7	78.7	77.4	78.1	77.1	77.2	76.8	78.7	78.7	77.4
	STD	9.3	9.7	10.3	9.5	10.9	10.3	10.8	10.1	11.0	11.3	10.2	10.3	10.4	10.1	11.0	11.3	10.2	10.3	10.4	10.3	10.1	11.0	11.3	10.2	10.3	10.4	10.3
	Median	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0
	Min	60.0	50.0	50.0	50.0	50.0	60.0	60.0	50.0	40.0	40.0	50.0	50.0	50.0	50.0	40.0	40.0	50.0	50.0	50.0	50.0	50.0	40.0	40.0	50.0	50.0	50.0	50.0
Heart Rate	Evaluated	107	106	102	90	88	86	82	106	105	101	90	88	82	106	105	101	90	88	87	82	106	105	101	90	88	87	82
	Mean	75.5	76.9	78.4	76.2	77.3	76.7	76.7	78.7	81.1	82.5	80.8	80.4	81.1	78.7	81.1	82.5	80.8	80.4	81.1	80.3	78.7	81.1	82.5	80.8	80.4	81.1	80.3
	STD	8.4	9.7	9.5	8.8	8.0	9.6	9.9	9.3	11.8	11.4	11.9	9.0	10.5	9.3	11.8	11.4	11.9	9.0	10.5	10.8	9.3	11.8	11.4	11.9	9.0	10.5	10.8
	Median	74.0	76.0	78.0	75.0	76.0	76.0	76.0	78.0	80.0	80.0	80.0	80.0	80.0	78.0	80.0	80.0	80.0	80.0	80.0	80.0	78.0	80.0	80.0	80.0	80.0	80.0	80.0
	Min	60.0	52.0	54.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	61.0	62.0	60.0	60.0	60.0	60.0	61.0	62.0	60.0	60.0	60.0	60.0	60.0	61.0	62.0	60.0	60.0
Max	110.0	105.0	100.0	104.0	100.0	100.0	100.0	118.0	140.0	120.0	113.0	116.0	125.0	118.0	140.0	120.0	113.0	116.0	125.0	125.0	118.0	140.0	120.0	113.0	116.0	125.0	125.0	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 74

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Imipramine

Vital signs	LXING														STANDING																
	time interval							time interval							time interval							time interval									
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
S.B.P.	Evaluated	111	111	101	90	87	81	76	110	110	110	110	100	90	85	81	75	160.0	160.0	170.0	165.0	150.0	160.0	160.0	165.0	160.0	165.0	160.0	150.0	160.0	
	Mean	126.4	123.5	124.0	125.0	122.7	123.7	125.1	124.0	120.3	119.9	121.0	120.2	119.7	120.2	130.0	120.0	120.0	125.0	125.0	125.0	125.0	125.0	125.0	125.0	125.0	125.0	125.0	120.0	120.0	
	STD	13.1	12.8	12.7	13.5	11.7	12.9	14.9	12.6	14.3	13.9	13.9	14.0	12.6	15.2	100.0	95.0	95.0	95.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	80.0	80.0
	Median	130.0	120.0	120.0	125.0	125.0	125.0	126.5	125.0	120.0	120.0	120.0	120.0	120.0	120.0	100.0	95.0	95.0	95.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	80.0	80.0
	Min	100.0	95.0	95.0	95.0	92.0	90.0	90.0	90.0	80.0	80.0	80.0	80.0	80.0	80.0	100.0	95.0	95.0	95.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	80.0	80.0
D.B.P.	Evaluated	111	111	101	90	87	81	76	110	110	110	110	100	90	86	81	75	160.0	160.0	170.0	165.0	150.0	160.0	160.0	165.0	160.0	165.0	160.0	150.0	160.0	
	Mean	78.5	77.6	77.7	78.4	77.4	76.6	78.0	78.8	76.7	76.8	77.2	77.2	76.2	77.0	78.5	77.6	77.7	78.4	77.4	76.6	78.0	78.8	76.7	76.8	77.2	77.2	76.2	77.0		
	STD	9.4	8.5	8.9	9.9	9.3	10.2	10.7	8.9	8.1	9.3	9.6	10.7	9.9	9.5	50.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0
	Median	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	50.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0
	Min	50.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	50.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0
Heart Rate	Evaluated	104	100	93	86	82	76	71	99	96	90	83	77	69	67	100.0	100.0	105.0	105.0	110.0	100.0	100.0	105.0	105.0	105.0	105.0	105.0	100.0	100.0		
	Mean	77.2	77.6	76.3	78.3	78.6	78.3	79.1	79.6	80.4	80.3	81.5	81.3	79.4	82.0	77.2	77.6	76.3	78.3	78.6	78.3	79.1	79.6	80.4	80.3	81.5	81.3	79.4	82.0		
	STD	10.0	9.2	8.7	10.7	9.0	9.0	11.0	11.1	11.5	10.2	11.9	11.9	10.2	11.4	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
	Median	76.0	78.0	76.0	78.0	78.0	78.0	78.0	78.0	80.0	80.0	80.0	80.0	80.0	80.0	76.0	78.0	76.0	78.0	78.0	78.0	78.0	78.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0
	Min	56.0	60.0	56.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	56.0	60.0	56.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0
Max	112.0	100.0	107.0	110.0	100.0	112.0	110.0	110.0	128.0	134.0	112.0	124.0	132.0	111.0	112.0	100.0	107.0	110.0	100.0	112.0	110.0	110.0	128.0	134.0	112.0	124.0	132.0	111.0			

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PHARMACIA CNS R&D
REBONETTINE - PROTOCOL 2012/4/015
TABLE No.: 7/4

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Placebo

Vital signs	LYING														STANDING																																										
	time interval							time interval							time interval							time interval																																			
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42																													
S.B.P.	Evaluated	110	108	103	100	94	87	86	109	107	101	98	92	86	85	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5
	Mean	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5
	STD	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5
	Median	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5
	Min	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5
Max	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	123.3	124.7	124.3	124.9	125.4	123.6	122.5	122.0	123.7	122.5	123.1	123.6	122.0	122.5	
D.B.P.	Evaluated	110	107	103	100	94	87	86	109	106	101	98	92	86	85	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3
	Mean	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3
	STD	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3
	Median	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3
	Min	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3	76.7	77.6	76.2	77.1	78.5	76.6	75.8	77.1	78.0	76.9	76.7	78.6	77.6	76.3
Heart Rate	Evaluated	105	104	96	94	84	79	78	104	101	96	93	83	78	76	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3
	Mean	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3
	STD	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3
	Median	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3
	Min	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3	74.7	75.5	75.0	73.8	73.7	73.9	71.5	77.2	78.0	77.2	77.1	76.4	76.7	74.3

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 75

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ON CHANGES FROM BASELINE OBSERVED DURING TREATMENT ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Vital signs	LYING														STANDING													
	Time interval														Time interval													
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42										
S.B.P.	Evaluated	111	105	98	96	90	87	111	105	98	96	87	111	105	98	96	89	87										
	Mean	-1.4	-0.1	-2.0	-1.4	-1.2	-0.1	-2.1	-1.5	-3.2	-2.4	-1.9	-3.2	-2.4	-1.9	-3.2	-1.9	-3.2										
	STD	10.3	11.6	12.0	11.5	11.5	11.2	10.1	12.7	10.9	12.2	13.0	11.2	12.7	10.9	12.2	13.0	11.2										
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-5.0										
	Min	-34.0	-40.0	-40.0	-38.0	-26.0	-32.0	-44.0	-34.0	-30.0	-44.0	-60.0	-36.0	-44.0	-30.0	-44.0	-60.0	-36.0										
D.B.P.	Evaluated	32.0	30.0	20.0	30.0	25.0	36.0	35.0	40.0	20.0	30.0	25.0	30.0	40.0	20.0	30.0	25.0	30.0										
	Mean	-1.2	-1.4	-2.5	-0.8	-0.0	-0.4	-1.1	-1.1	-1.7	0.3	0.5	-0.9	-1.1	-1.7	0.3	0.5	-0.9										
	STD	6.5	8.3	8.9	9.5	9.2	9.4	7.2	7.7	8.0	8.4	9.5	8.4	7.7	8.0	8.4	9.5	8.8										
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0										
	Min	-20.0	-30.0	-30.0	-34.0	-30.0	-30.0	-26.0	-20.0	-30.0	-24.0	-40.0	-32.0	-20.0	-30.0	-24.0	-40.0	-32.0										
Heart Rate	Evaluated	106	102	90	88	86	82	105	101	90	88	82	105	101	90	88	87	82										
	Mean	1.6	2.7	0.3	1.4	1.0	1.4	2.4	3.6	1.8	1.2	2.1	1.1	2.4	1.8	1.2	2.1	1.1										
	STD	7.7	8.6	9.3	8.4	9.6	10.4	9.6	10.4	10.3	8.7	10.3	10.2	10.4	10.3	8.7	10.3	10.2										
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.5	0.0	0.0	1.0	0.0	0.5	0.0	0.0										
	Min	-20.0	-14.0	-26.0	-20.0	-26.0	-22.0	-19.0	-15.0	-24.0	-20.0	-34.0	-34.0	-15.0	-24.0	-20.0	-34.0	-34.0										
Max	32.0	28.0	36.0	20.0	30.0	30.0	36.0	47.0	40.0	20.0	36.0	25.0	47.0	40.0	20.0	36.0	25.0											

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PHARMACIA CNS R&D

REBOXYLINE - PROTOCOL 20124/015
TABLE No.: 75

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ON CHANGES FROM BASELINE OBSERVED DURING TREATMENT ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Imipramine

Vital signs	LYING														STANDING													
	Time interval														Time interval													
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42										
S.B.P.	Evaluated	111	101	90	87	81	76	110	100	90	86	81	75	110	100	90	86	81	75									
	Mean	-2.9	-2.7	-2.1	-4.1	-2.4	-1.9	-3.7	-4.3	-3.1	-4.1	-3.8	-3.6	-3.7	-4.3	-3.1	-4.1	-3.8	-3.6									
	STD	8.8	12.6	11.5	11.5	12.7	14.6	12.3	13.6	12.9	13.2	14.5	16.6	12.3	13.6	12.9	13.2	14.5	16.6									
	Median	0.0	0.0	0.0	0.0	-4.0	0.0	0.0	0.0	0.0	-1.0	-5.0	-3.0	0.0	0.0	0.0	-1.0	-5.0	-3.0									
	Min	-38.0	-60.0	-40.0	-50.0	-40.0	-41.0	-55.0	-70.0	-65.0	-45.0	-55.0	-55.0	-55.0	-70.0	-65.0	-45.0	-55.0	-55.0									
	Max	20.0	30.0	30.0	20.0	30.0	40.0	35.0	20.0	25.0	30.0	30.0	40.0	35.0	20.0	25.0	30.0	30.0	40.0									
D.B.P.	Evaluated	111	101	90	87	81	76	110	100	90	86	81	75	110	100	90	86	81	75									
	Mean	-0.9	-1.1	-0.5	-1.1	-1.6	-0.4	-2.1	-2.4	-2.1	-2.1	-2.8	-2.0	-2.1	-2.4	-2.1	-2.1	-2.8	-2.0									
	STD	8.7	9.9	9.5	8.5	9.8	8.9	8.4	8.9	8.3	9.8	9.7	9.9	8.4	8.9	8.3	9.8	9.7	9.9									
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0									
	Min	-30.0	-30.0	-24.0	-20.0	-20.0	-20.0	-30.0	-30.0	-30.0	-30.0	-30.0	-30.0	-30.0	-30.0	-30.0	-30.0	-30.0	-30.0									
	Max	20.0	30.0	26.0	20.0	20.0	20.0	30.0	20.0	20.0	20.0	20.0	20.0	30.0	20.0	20.0	20.0	20.0	20.0									
Heart Rate	Evaluated	100	93	86	82	76	71	96	90	83	77	69	67	96	90	83	77	69	67									
	Mean	0.1	-0.9	0.5	1.3	1.3	1.6	0.5	0.4	1.0	1.2	-0.2	1.7	0.5	0.4	1.0	1.2	-0.2	1.7									
	STD	6.6	9.1	11.1	8.4	10.3	11.8	9.0	9.7	11.2	9.2	9.4	11.0	9.0	9.7	11.2	9.2	9.4	11.0									
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0	2.0									
	Min	-24.0	-28.0	-31.0	-21.0	-24.0	-28.0	-28.0	-27.0	-34.0	-21.0	-30.0	-24.0	-28.0	-27.0	-34.0	-21.0	-30.0	-24.0									
	Max	24.0	30.0	40.0	20.0	42.0	50.0	30.0	30.0	30.0	26.0	28.0	40.0	30.0	30.0	30.0	26.0	28.0	40.0									

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

TABLE No.: 75

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ON CHANGES FROM BASELINE OBSERVED DURING TREATMENT ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Placebo

Vital signs	LYING														STANDING													
	Time interval														Time interval													
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42										
S.B.P.	Evaluated	108	103	100	94	87	86	107	101	98	92	86	107	101	98	92	86	85										
	Mean	1.4	1.4	1.8	1.9	0.2	-0.9	1.6	0.5	0.6	1.8	-0.3	1.6	0.5	0.6	1.8	-0.3	-0.1										
	STD	10.7	11.9	12.6	12.5	12.4	12.4	11.0	12.7	13.0	12.9	13.3	12.2	12.7	13.0	12.9	13.3	12.2										
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0										
	Min	-30.0	-40.0	-30.0	-40.0	-35.0	-40.0	-40.0	-30.0	-50.0	-35.0	-50.0	-30.0	-50.0	-35.0	-50.0	-35.0	-30.0										
D.B.P.	Evaluated	40.0	40.0	36.0	40.0	30.0	30.0	40.0	55.0	35.0	50.0	30.0	40.0	55.0	35.0	50.0	30.0	30.0										
	Mean	0.8	-0.2	0.6	2.0	0.2	-0.8	0.7	-0.2	-0.4	1.8	1.0	0.7	-0.2	-0.4	1.8	1.0	-0.8										
	STD	7.7	8.0	9.0	9.1	9.2	9.9	8.4	7.8	10.9	9.8	8.4	7.7	8.4	10.9	9.8	9.0	8.4										
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0										
	Min	-30.0	-30.0	-30.0	-30.0	-30.0	-40.0	-40.0	-30.0	-25.0	-40.0	-30.0	-30.0	-30.0	-40.0	-30.0	-30.0	-30.0										
Heart Rate	Evaluated	104	96	94	84	79	78	101	96	93	83	76	101	96	93	83	78	76										
	Mean	0.8	0.5	-0.2	-0.0	0.5	-1.6	0.7	0.2	0.2	0.1	0.3	0.7	0.2	0.2	0.1	0.3	-1.8										
	STD	7.1	7.5	9.0	8.3	8.2	8.6	7.6	8.8	10.2	9.1	10.2	7.6	8.8	10.2	9.1	9.3	10.2										
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0										
	Min	-20.0	-20.0	-30.0	-26.0	-24.0	-32.0	-30.0	-36.0	-30.0	-26.0	-30.0	-36.0	-30.0	-36.0	-26.0	-30.0	-36.0										
Max	30.0	30.0	36.0	28.0	24.0	22.0	24.0	24.0	35.0	35.0	29.0	24.0	35.0	35.0	29.0	23.0	24.0											

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 76

BLOOD PRESSURE AND HEART RATE: NUMBER AND PERCENTAGE OF PATIENTS WITH DECREASE OR INCREASE vs BASELINE OF CLINICAL RELEVANCE ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Vital signs		LYING												STANDING												
		time intervals						time intervals						time intervals						time intervals						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
S.B.P.	Evaluated	No	111	105	98	96	90	87	111	105	98	96	89	87	111	105	98	96	89	87	111	105	98	96	89	87
	Decrease (1)	No	1		3		1		1		4		1		1		4		1		1		1		1	
	Z	0.9		3.1		1.1		1.1		3.8		1.0		1.1		3.8		1.0		1.0		1.1		1.0		1.1
D.B.P.	Evaluated	No	111	105	98	96	90	87	111	105	97	96	89	87	111	105	97	96	89	87	111	105	97	96	89	87
	Decrease (1)	No	2	4	5	1	3	2			1		1		1		2		1		2		1		2	
	Z	1.8	3.8	5.1	1.0	3.3	2.3			1.0	2.1	1.0	1.1		1.0	2.1	1.0	1.1		1.1	2.3		1.0	1.1	2.3	
Both	Evaluated	No	111	105	98	96	90	87	111	105	97	96	89	87	111	105	97	96	89	87	111	105	97	96	89	87
	Decrease (1)	No	1	1	1	1			2		3		2		2		3		2		2		2		2	
	Z	1.0	1.0	1.0	1.0			1.8		2.9		1.0		2.2		2.9		1.0		2.2	1.1		1.0		2.2	
Heart rate	Evaluated	No	106	102	90	88	86	82	105	101	90	88	87	82	105	101	90	88	87	82	105	101	90	88	87	82
	Decrease (1)	No	3	1	4		2	2	1		1		2		1		1		2		1		1		2	
	Z	2.8	1.0	4.4		2.3	2.4	1.0	1.1		1.1		2.3		1.1		1.1		2.3		1.1		1.1		2.3	
Increase (2)	No	5	11	7	8	8	11	8	11	8	11	8	11	8	11	8	11	8	11	8	11	8	11	8	11	9
	Z	4.7	10.8	7.8	9.1	9.3	13.4	7.6	10.9	8.9	6.8	9.2	11.0	8.9	6.8	9.2	11.0	8.9	6.8	9.2	11.0	8.9	6.8	9.2	11.0	

(1) decrease => 20 % of baseline value
(2) increase => 20 % of baseline value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 76

BLOOD PRESSURE AND HEART RATE: NUMBER AND PERCENTAGE OF PATIENTS WITH DECREASE OR INCREASE vs BASELINE OF CLINICAL RELEVANCE ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Imipramine

Vital signs		LYING												STANDING												
		time intervals						time intervals						time intervals						time intervals						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
S.B.P.	Evaluated	No	111	101	90	87	81	76																		
	Decrease (1)	No	1	3	2	3	2	6																		
	X	0.9	3.0	2.2	3.4	2.5	7.9																			
D.B.P.	Evaluated	No	111	101	90	87	81	76																		
	Decrease (1)	No	4	6	3	3	6	2																		
	X	3.6	5.9	3.3	3.4	7.4	2.6																			
Both	Evaluated	No	111	101	90	87	81	76																		
	Decrease (1)	No	1	1	1	1																				
	X	0.9	1.0	1.1	1.1																					
Heart rate	Evaluated	No	100	93	86	82	76	71																		
	Decrease (1)	No	1	4	3	1	2	3																		
	X	1.0	4.3	3.5	1.2	2.6	4.2																			

(1) decrease => 20 % of baseline value
(2) increase => 20 % of baseline value

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PHARMACIA CNS R&D

REBOXYLINE - PROTOCOL 20124/015
TABLE No. : 76

BLOOD PRESSURE AND HEART RATE: NUMBER AND PERCENTAGE OF PATIENTS WITH DECREASE OR INCREASE vs BASELINE OF CLINICAL RELEVANCE ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Placebo

Vital signs		LYING												STANDING																												
		time intervals						time intervals						time intervals						time intervals																						
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42																	
S.B.P.	Evaluated	No	108	103	100	94	87	86	107	101	98	92	86	85	No	108	103	100	94	87	86	107	101	98	92	86	85	No	108	103	100	94	87	86	107	101	98	92	86	85		
	Decrease (1)	No	1	1	2	3	1	1	1	1	2	1	2	1	No	1	1	2	3	1	1	1	1	2	1	2	1	No	1	1	2	3	1	1	1	1	2	1	2	1		
	%	0.9	1.0	1.0	2.1	3.4	1.2	0.9	0.9	0.9	2.0	1.1	2.3	1.2	%	0.9	1.0	1.0	2.1	3.4	1.2	0.9	0.9	2.0	1.1	2.3	1.2	%	0.9	1.0	1.0	2.1	3.4	1.2	0.9	0.9	2.0	1.1	2.3	1.2		
D.B.P.	Evaluated	No	107	103	100	96	87	86	106	101	98	92	86	85	No	107	103	100	96	87	86	106	101	98	92	86	85	No	107	103	100	96	87	86	106	101	98	92	86	85		
	Decrease (1)	No	2	3	3	1	4	2	5	3	5	2	1	1	No	2	3	3	1	4	2	5	3	5	2	1	1	No	2	3	3	1	4	2	5	3	5	2	1	1		
	%	1.9	2.9	3.0	1.1	4.6	2.3	4.7	3.0	4.7	5.1	2.2	1.2	1.2	%	1.9	2.9	3.0	1.1	4.6	2.3	4.7	3.0	4.7	5.1	2.2	1.2	1.2	%	1.9	2.9	3.0	1.1	4.6	2.3	4.7	3.0	4.7	5.1	2.2	1.2	1.2
Both	Evaluated	No	107	103	100	94	87	86	106	101	98	92	86	85	No	107	103	100	94	87	86	106	101	98	92	86	85	No	107	103	100	94	87	86	106	101	98	92	86	85		
	Decrease (1)	No	1	1	1	1	1	1	1	1	2	2	1	1	No	1	1	1	1	1	1	1	1	2	2	1	1	No	1	1	1	1	1	1	1	1	2	2	1	1		
	%	0.9	1.0	1.0	1.1	1.1	1.2	1.2	1.0	1.0	2.0	2.2	1.2	1.2	%	0.9	1.0	1.0	1.1	1.1	1.2	1.0	1.0	2.0	2.2	1.2	1.2	%	0.9	1.0	1.0	1.1	1.1	1.2	1.0	1.0	2.0	2.2	1.2	1.2		
Heart rate	Evaluated	No	104	96	94	84	79	78	101	96	93	83	78	76	No	104	96	94	84	79	78	101	96	93	83	78	76	No	104	96	94	84	79	78	101	96	93	83	78	76		
	Decrease (1)	No	1	1	3	1	2	4	2	2	3	1	3	6	No	1	1	3	1	2	4	2	2	3	1	3	6	No	1	1	3	1	2	4	2	2	3	1	3	6		
	%	1.0	1.0	3.2	1.2	2.5	5.1	5.1	2.0	2.1	3.2	1.2	3.8	7.9	%	1.0	1.0	3.2	1.2	2.5	5.1	2.0	2.1	3.2	1.2	3.8	7.9	%	1.0	1.0	3.2	1.2	2.5	5.1	2.0	2.1	3.2	1.2	3.8	7.9		
Increase (2)	No	6	7	4	5	6	3	5	5	6	6	7	3	3	No	6	7	4	5	6	3	5	5	6	6	7	3	3	No	6	7	4	5	6	3	5	5	6	6	7	3	3
	%	5.8	7.3	4.3	6.0	7.6	3.8	5.0	5.2	6.5	7.2	9.0	3.9	3.9	%	5.8	7.3	4.3	6.0	7.6	3.8	5.0	5.2	6.5	7.2	9.0	3.9	3.9	%	5.8	7.3	4.3	6.0	7.6	3.8	5.0	5.2	6.5	7.2	9.0	3.9	3.9

(1) decrease => 20 % of baseline value
(2) increase => 20 % of baseline value

PHARMACIA CNS R&D 550082

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 77

BLOOD PRESSURE AND HEART RATE: ABSOLUTE NUMBER OF PATIENTS SHOWING CLINICALLY RELEVANT CHANGES, COMPARED TO BASELINE, ONCE, TWICE OR MORE TIMES DURING THE THERAPY

Assigned treatment / Vital signs			LYING			STANDING		
			1 time	2 times	3 times or more	1 time	2 times	3 times or more
Imipramine	S.B.P. (1)	Decrease	4		1	5	1	
		Increase						
	D.B.P. (2)	Decrease	6	3	4	8	5	1
		Increase	3	1		2		
	BOTH (1 & 2)	Decrease				6		1
HEART RATE (3)	Increase	3	2		4	3	1	
Placebo	S.B.P. (1)	Decrease	1		1		2	1
		Increase	3			3	1	
	D.B.P. (2)	Decrease	5	2	2	5	3	2
		Increase	3					
	BOTH (1 & 2)	Decrease				4		
	HEART RATE (3)	Decrease	1			1		
		Increase	1			2		
Reboxetine	S.B.P. (1)	Decrease				3	1	
		Increase	1					
	D.B.P. (2)	Decrease	5	2	2	3	2	
		Increase	8			2	1	
	BOTH (1 & 2)	Decrease	1			3	1	1
		Increase	1			2		
	HEART RATE (3)	Increase	9	1	1	8	4	1

- (1) decrease => 20 % vs baseline value and systolic value <= 100 mmHg
 increase => 20 % vs baseline value and systolic value >= 160 mmHg
 (2) decrease => 20 % vs baseline value and diastolic value <= 70 mmHg
 increase => 20 % vs baseline value and diastolic value >= 100 mmHg
 (3) decrease => 20 % vs baseline value and heart rate value <= 50 beats/min
 increase => 20 % vs baseline value and heart rate value >= 100 beats/min

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 78
 BLOOD PRESSURE: NUMBER AND PERCENTAGE OF PATIENTS WITH ORTHOSTATIC HYPOTENSION (*) BEFORE AND DURING THE STUDY
 ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment / Vital signs	According to time interval											
	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70
Imipramine	Eval.	108	110	110	100	90	86	81	75			
	No.	2	4	3	2	1	2	1	1			
	Z	1.9	3.6	3.0	2.2	1.2	2.5	1.3				
	Mean	55.0	37.5	43.3	30.0	30.0	35.0	40.0				
	Max.	60.0	55.0	60.0	30.0	30.0	40.0	40.0				
Placebo	Eval.	107	109	107	101	98	92	86	85			
	No.			2	1	1						
	Z			2.0	1.0	1.1						
	Mean			30.0	58.0	36.0						
	Max.			30.0	58.0	36.0						
Reboxetine	Eval.	110	111	111	105	98	96	89	87			
	No.	2	3	3	4	2	3	2	4			
	Z	1.8	2.7	2.7	3.8	2.0	3.1	2.2	4.6			
	Mean	42.5	38.3	33.7	39.0	35.0	40.0	55.0	48.0			
	Max.	45.0	45.0	35.0	50.0	40.0	50.0	60.0	60.0			

(*) orthostatic hypotension = decrease of systolic blood pressure in standing position => 30 mm hg as compared to lying position

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 79

BODY WEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Reboxetine

Sex		Time interval									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Female	Evaluated	68	68	65	59	56	52	49			
	Mean	64.3	64.2	64.5	64.2	63.4	63.0	63.4			
	STD	14.5	14.3	14.3	14.6	13.5	13.2	13.3			
	Median	64.0	63.0	64.0	62.8	62.5	61.8	63.0			
	Min	38.0	40.0	41.0	40.0	38.0	38.0	39.0			
	Max	116.0	116.0	115.0	115.0	97.0	97.0	97.0			
Male	Evaluated	42	42	40	38	40	38	38			
	Mean	76.5	76.2	76.8	77.1	76.9	77.2	76.7			
	STD	13.3	13.0	12.6	12.7	12.2	12.3	12.2			
	Median	75.5	75.0	75.6	76.0	75.7	76.0	75.8			
	Min	62.0	61.0	60.0	60.0	60.0	61.0	62.0			
	Max	141.0	138.0	136.0	135.0	133.0	132.0	130.0			
Total	Evaluated	110	110	105	97	96	90	87			
	Mean	68.9	68.8	69.2	69.3	69.0	69.0	69.2			
	STD	15.2	14.9	14.9	15.2	14.5	14.5	14.4			
	Median	67.5	67.3	68.0	68.0	69.0	69.0	68.0			
	Min	38.0	40.0	41.0	40.0	38.0	38.0	39.0			
	Max	141.0	138.0	136.0	135.0	133.0	132.0	130.0			

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

TABLE No. : 79

BODY WEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Imipramine

Sex		Time interval									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Female	Evaluated	75	74	69	59	58	54	49			
	Mean	63.4	63.5	62.5	62.3	63.5	63.7	63.4			
	STD	12.1	12.0	11.3	11.6	11.6	11.8	11.8			
	Median	61.0	61.1	61.0	60.0	61.0	61.1	61.5			
	Min	40.0	41.0	41.0	41.5	41.5	42.0	40.0			
	Max	99.5	99.0	86.5	87.7	88.0	91.5	91.0			
Male	Evaluated	36	36	32	29	29	27	26			
	Mean	76.4	76.2	77.4	78.4	77.9	78.3	78.4			
	STD	10.9	10.8	10.4	10.0	9.6	9.6	10.2			
	Median	76.5	75.3	76.5	77.0	77.0	77.0	76.5			
	Min	55.0	55.0	61.0	63.5	63.5	63.5	61.0			
	Max	99.0	99.0	99.0	99.0	99.0	99.0	99.0			
Total	Evaluated	111	110	101	88	87	81	75			
	Mean	67.6	67.6	67.2	67.6	68.3	68.5	68.6			
	STD	13.1	13.0	13.0	13.4	12.9	13.1	13.3			
	Median	67.0	66.0	66.0	66.3	68.0	68.0	70.0			
	Min	40.0	41.0	41.0	41.5	41.5	42.0	40.0			
	Max	99.5	99.0	99.0	99.0	99.0	99.0	99.0			

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PHARMACIA CNS R&D

ZEBONETINE - PROTOCOL 20124/015
TABLE No.: 79

BODY WEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Placebo

Sex		Time interval										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70
Female	Evaluated	51	51	48	47	43	41	40				
	Mean	63.9	63.7	64.2	64.3	64.4	65.1	64.7				
	STD	12.4	12.4	12.3	12.6	12.3	13.2	12.9				
	Median	61.0	61.0	61.0	61.0	61.5	61.5	61.5				
	Min	41.0	41.0	41.0	40.5	41.0	41.0	41.5				
	Max	96.2	96.0	96.0	96.3	98.0	98.0	96.5				
Male	Evaluated	58	56	53	51	48	46	46				
	Mean	75.4	75.6	75.4	76.0	75.7	75.4	75.6				
	STD	13.8	14.0	14.3	13.8	14.0	14.2	14.2				
	Median	74.5	75.0	75.0	74.3	74.7	74.1	74.1				
	Min	48.5	48.3	48.2	52.0	53.0	53.0	53.0				
	Max	133.0	133.0	133.0	133.0	133.0	133.0	133.0				
Total	Evaluated	109	107	101	98	91	87	86				
	Mean	70.0	70.0	70.1	70.4	70.3	70.5	70.5				
	STD	14.3	14.5	14.5	14.4	14.4	14.6	14.6				
	Median	68.0	69.0	69.0	68.5	69.0	69.0	69.0				
	Min	41.0	41.0	41.0	40.5	41.0	41.0	41.5				
	Max	133.0	133.0	133.0	133.0	133.0	133.0	133.0				

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 20

BODY WEIGHT: NUMBER AND PERCENTAGE OF PATIENTS WITH VALUES LOWER OR HIGHER (*) THAN PRE-TREATMENT AT EACH EVALUATION TIME, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Reboxetine

Sex		Time interval											
		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42	
		No	%	No	%	No	%	No	%	No	%	No	%
Female	Lower	1	1.5	2	3.1	2	3.4	2	3.6	5	9.6	7	14.3
	Same	65	95.6	61	93.8	55	93.2	48	85.7	43	82.7	38	77.6
	Higher	2	2.9	2	3.1	2	3.4	6	10.7	4	7.7	4	8.2
	Total	68	100.0	65	100.0	59	100.0	56	100.0	52	100.0	49	100.0
Male	Lower					1	2.6	3	7.5	2	5.3		
	Same	41	97.6	38	95.0	36	94.7	36	90.0	35	92.1	35	92.1
	Higher	1	2.4	2	5.0	1	2.6	1	2.5	1	2.6	3	7.9
	Total	42	100.0	40	100.0	38	100.0	40	100.0	38	100.0	38	100.0
Total	Lower	1	0.9	2	1.9	3	3.1	5	5.2	7	7.8	7	8.0
	Same	106	96.4	99	94.3	91	93.8	84	87.5	78	86.7	73	83.9
	Higher	3	2.7	4	3.8	3	3.1	7	7.3	5	5.6	7	8.0
	Total	110	100.0	105	100.0	97	100.0	96	100.0	90	100.0	87	100.0

(*) LOWER: decrease > 2.5 Kg.
HIGHER: increase > 2.5 Kg.

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PHARMACIA CNS R&D

REBOXYTINE - PROTOCOL 20124/015
TABLE No. : 80

BODY WEIGHT: NUMBER AND PERCENTAGE OF PATIENTS WITH VALUES LOWER OR HIGHER (*) THAN PRE-TREATMENT AT EACH EVALUATION TIME, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Inipramine

Sex		Time interval											
		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42	
		No	Z	No	Z	No	Z	No	Z	No	Z	No	Z
Female	Lower					3	5.1	4	6.9	6	11.1	11	22.4
	Same	73	98.6	66	95.7	53	89.8	51	87.9	44	81.5	36	73.5
	Higher	1	1.4	3	4.3	3	5.1	3	5.2	4	7.4	2	4.1
	Total	74	100.0	69	100.0	59	100.0	58	100.0	54	100.0	49	100.0
Male	Lower					2	6.9	1	3.4	1	3.7	2	7.7
	Same	35	97.2	31	96.9	26	89.7	27	93.1	23	85.2	22	84.6
	Higher	1	2.8	1	3.1	1	3.4	1	3.4	3	11.1	2	7.7
	Total	36	100.0	32	100.0	29	100.0	29	100.0	27	100.0	26	100.0
Total	Lower					5	5.7	5	5.7	7	8.6	13	17.3
	Same	108	98.2	97	96.0	79	89.8	78	89.7	67	82.7	58	77.3
	Higher	2	1.8	4	4.0	4	4.5	4	4.6	7	8.6	4	5.3
	Total	110	100.0	101	100.0	88	100.0	87	100.0	81	100.0	75	100.0

(*) LOWER: decrease > 2.5 Kg.
HIGHER: increase > 2.5 Kg.

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REBOXYTINE - PROTOCOL 20124/015
TABLE No.: 80

BODY WEIGHT: NUMBER AND PERCENTAGE OF PATIENTS WITH VALUES LOWER OR HIGHER (*) THAN PRE-TREATMENT AT EACH EVALUATION TIME, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Placebo

Sex		Time interval											
		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42	
		No	%	No	%	No	%	No	%	No	%	No	%
Female	Lower	1	2.0	1	2.1	2	4.3	1	2.3	3	7.3	3	7.5
	Same	48	94.1	45	93.8	44	93.6	41	95.3	38	92.7	36	90.0
	Higher	2	3.9	2	4.2	1	2.1	1	2.3			1	2.5
	Total	51	100.0	48	100.0	47	100.0	43	100.0	41	100.0	40	100.0
Male	Lower					2	3.9	1	2.1	2	4.3	1	2.2
	Same	56	100.0	51	96.2	47	92.2	44	91.7	42	91.3	43	93.5
	Higher			2	3.8	2	3.9	3	6.3	2	4.3	2	4.3
	Total	56	100.0	53	100.0	51	100.0	48	100.0	46	100.0	46	100.0
Total	Lower	1	0.9	1	1.0	4	4.1	2	2.2	5	5.7	4	4.7
	Same	104	97.2	96	95.0	91	92.9	85	93.4	80	92.0	79	91.9
	Higher	2	1.9	4	4.0	3	3.1	4	4.4	2	2.3	3	3.5
	Total	107	100.0	101	100.0	98	100.0	91	100.0	87	100.0	86	100.0

(*) LOWER: decrease > 2.5 Kg.
HIGHER: increase > 2.5 Kg.

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REBOXETINE - PROTOCOL 20124/015
TABLE No. 1 81

E.C.G.: NUMBER AND PERCENTAGE OF PATIENTS WITH ABNORMAL E.C.G. ACCORDING TO TIME INTERVALS, BY ASSIGNED TREATMENT AND SEX

Assigned treatment/Sex		Female			Male			Total			
		Screening	1-21 days	22-42 days	Screening	1-21 days	22-42 days	Screening	1-21 days	22-42 days	
Imipramine	Eval.	No.	63	54	50	28	26	25	91	80	75
	Normal	No.	53	37	39	24	21	22	77	58	61
	Z		84.13	68.52	78.00	85.71	80.77	88.00	84.62	72.50	81.33
Placebo	Abnormal	No.	10	17	11	4	5	3	14	22	14
	Eval.	Z	15.87	31.48	22.00	14.29	19.23	12.00	15.38	27.50	18.67
	Normal	No.	44	38	37	51	48	45	95	86	82
Reboxetine	Normal	No.	39	34	33	46	40	40	85	74	79
	Z		88.64	89.47	89.19	90.20	83.33	88.89	89.47	86.05	89.02
	Abnormal	No.	5	4	4	5	8	5	10	12	9
Reboxetine	Eval.	Z	11.36	10.53	10.81	9.80	16.67	11.11	10.53	13.95	10.98
	Normal	No.	54	50	45	37	36	34	91	86	79
	Z		43	43	39	33	30	30	76	73	69
Abnormal	Eval.	Z	79.63	86.00	86.67	89.19	83.33	88.24	83.52	84.88	87.34
	Normal	No.	11	7	6	4	6	4	15	13	10
	Z		20.37	14.00	13.33	10.81	16.67	11.76	16.48	15.12	12.66

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 82
 E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH NORMAL OR ABNORMAL E.C.G. VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment/E.C.G. at Baseline		Time interval					
		1-21 days			22-42 days		
		Abnormal	Normal	Total	Abnormal	Normal	Total
Imipramine	No.	11	2	6	3		
	Z	84.6	15.4	66.7	33.3		
	No.	11	56	8	58		
	Z	16.4	83.6	12.1	87.9		
Total		22	58	14	61		
Z		27.5	72.5	18.7	81.3		
Placebo	No.	7	2	4	4		
	Z	77.8	22.2	50.0	50.0		
	No.	5	72	5	69		
	Z	6.5	93.5	6.8	93.2		
Total		12	74	9	73		
Z		14.0	86.0	11.0	89.0		
Reboxetine	No.	7	6	9	3		
	Z	53.8	46.2	75.0	25.0		
	No.	6	67	1	66		
	Z	8.2	91.8	1.5	98.5		
Total		13	73	10	69		
Z		15.1	84.9	12.7	87.3		

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REBOXETINE - PROTOCOL 2012/4/015

TABLE No.: 85

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH NORMAL OR ABNORMAL E.C.G. VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment/E.C.G. at Baseline	Last assessment							
	Abnormal			Normal			Total	
	No.	%	%	No.	%	%	No.	%
Imipramine	Abnormal	10	71.4	4	28.6	14	100.0	
	Normal	11	14.3	66	85.7	77	100.0	
	Total	21	23.1	70	76.9	91	100.0	
Placebo	Abnormal	6	60.0	4	40.0	10	100.0	
	Normal	5	5.9	80	94.1	85	100.0	
	Total	11	11.6	84	88.4	95	100.0	
Reboxetine	Abnormal	10	66.7	5	33.3	15	100.0	
	Normal	2	2.6	74	97.4	76	100.0	
	Total	12	13.2	79	86.8	91	100.0	

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REBOXETINE - PROTOCOL 20124/015

TABLE No.: 84

E.C.G.: NUMBER AND PERCENTAGE OF E.C.G. ABNORMALITIES OBSERVED DURING THE STUDY, BY ASSIGNED TREATMENT

E.C.G. abnormality type	Imipramine						Placebo						Reboxetine						
	Screening		1-21 days		22-42 days		Screening		1-21 days		22-42 days		Screening		1-21 days		22-42 days		
	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	
Evaluated Pt	91	100.0	80	100.0	75	100.0	95	100.0	86	100.0	82	100.0	91	100.0	86	100.0	79	100.0	
ATRIAL ECTOPIC BEATS - OCCASIONAL	1	1.1	2	2.5							1	1.2	1	1.1	1	1.2	1	1.3	
ATRIAL FIBRILLATION / FLUTTER																			
CONDUCTION DISORDER							1	1.1							1	1.1			
LEFT ANTERIOR HEMIBLOCK	1	1.1	1	1.2	1	1.3			1	1.2									
LEFT AXIAL DEVIATION	1	1.1	2	2.5	1	1.3	1	1.1	1	1.2	1	1.2							
LEFT BUNDLE BRANCH BLOCK	1	1.1	1	1.2	1	1.3													
LEFT VENTRICULAR HYPERTROPHY			1	1.2			1	1.1						2	2.2	2	2.3	2	2.5
MYOCARDIAL ISCHEMIA	3	3.3	2	2.5	2	2.7	1	1.1	1	1.2									
NON SPECIFIC ST-T WAVE CHANGES	1	1.1							1	1.2				3	3.3	1	1.2	2	2.5
OTHER	1	1.1	2	2.5															
PREVIOUS MYOCARDIAL INFARCTION			1	1.2										1	1.1	1	1.2	1	1.3
RIGHT BUNDLE BRANCH BLOCK	1	1.1	4	5.0	3	4.0	1	1.1			1	1.2							
RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	1	1.1							1	1.2									
RIPOLARIZATION DISTURBANCES							2	2.1	1	1.2				2	2.2	1	1.2	1	1.3
SINUS BRADYCARDIA (< 60)	4	4.4	1	1.2	2	2.7	3	3.2	6	7.0	5	6.1	5	5.5	1	1.2	1	1.3	
SINUS TACHYCARDIA (> 100)	3	3.3	7	8.8	6	8.0	1	1.1	1	1.2	1	1.2	2	2.2	3	3.5	2	2.5	
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	1	1.1	2	2.5					1	1.2	1	1.2							

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REBOXETINE - PROTOCOL 20124/015
TABLE No.: 85

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

		Last assessment					
		Absent		Present		Total	
		No	Z	No	Z	No	Z
E.C.G. Abnormality	Baseline						
	Absent	89	98.9	1	1.1	90	100.0
	Present	1	100.0			1	100.0
	Total	90	98.9	1	1.1	91	100.0
ATRIAL FIBRILLATION / FLUTTER	Baseline						
	Absent	90	100.0			90	100.0
	Present			1	100.0	1	100.0
	Total	90	98.9	1	1.1	91	100.0
CONDUCTION DISORDER	Baseline						
	Absent	90	100.0			90	100.0
	Present			1	100.0	1	100.0
	Total	90	98.9	1	1.1	91	100.0
LEFT ANTERIOR HEMIBLOCK	Baseline						
	Absent	91	100.0			91	100.0
	Total	91	100.0			91	100.0
	Baseline						
LEFT AXIAL DEVIATION	Absent	91	100.0			91	100.0
	Total	91	100.0			91	100.0
	Baseline						
	Absent	91	100.0			91	100.0
LEFT BUNDLE BRANCH BLOCK	Total	91	100.0			91	100.0
	Baseline						
	Absent	91	100.0			91	100.0
	Total	91	100.0			91	100.0

(CONTINUED)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No. : 55

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

		Last assessment						Total			
		Absent		Present		Total		No	Z		
		No	Z	No	Z	No	Z				
E.C.G. Abnormality	Baseline										
	Absent	89	100.0					89	100.0		
	Present			2	100.0	2	100.0	2	100.0		
	Total	89	97.8	2	2.2	91	100.0				
MYOCARDIAL ISCHEMIA	Baseline										
	Absent	91	100.0					91	100.0		
	Total	91	100.0					91	100.0		
NON SPECIFIC ST-T WAVE CHANGES	Baseline										
	Absent	88	100.0					88	100.0		
	Present	1	33.3	2	66.7	3	100.0				
	Total	89	97.8	2	2.2	91	100.0				
OTHER	Baseline										
	Absent	91	100.0					91	100.0		
	Total	91	100.0					91	100.0		
PREVIOUS MYOCARDIAL INFARCTION	Baseline										
	Absent	90	100.0					90	100.0		
	Present			1	100.0	1	100.0	1	100.0		
	Total	90	98.9	1	1.1	91	100.0				
RIGHT BUNDLE BRANCH BLOCK	Baseline										
	Absent	91	100.0					91	100.0		
	Total	91	100.0					91	100.0		

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PHARMACIA CMS RD
 REBOXYLINE - PROTOCOL 20124/015
 TABLE No.: 55

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

		Last assessment						Total			
		Absent		Present		Total		No	%		
		No	%	No	%	No	%				
E.C.G. Abnormality RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	Baseline										
	Absent	91	100.0					91	100.0		
	Total	91	100.0					91	100.0		
BIPOLARIZATION DISTURBANCES	Baseline										
	Absent	89	100.0					89	100.0		
	Present	1	50.0	1	50.0			2	100.0		
Total	90	98.9	1	1.1			91	100.0			
SINUS BRADYCARDIA (< 60)	Baseline										
	Absent	86	100.0					86	100.0		
	Present	4	80.0	1	20.0			5	100.0		
Total	90	98.9	1	1.1			91	100.0			
SINUS TACHYCARDIA (> 100)	Baseline										
	Absent	87	97.8	2	2.2			89	100.0		
	Present	1	50.0	1	50.0			2	100.0		
Total	88	96.7	3	3.3			91	100.0			
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	Baseline										
	Absent	91	100.0					91	100.0		
	Total	91	100.0					91	100.0		

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PHARMACIA CNS R&D
REBOXYETINE - PROTOCOL 20124/015
TABLE No.: 85

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Imipramine

		Last assessment					
		Absent			Present		
		No	Z	%	No	Z	%
E.C.G. Abnormality	Baseline						
	Absent	90	100.0				90 100.0
	Present	1	100.0				1 100.0
	Total	91	100.0				91 100.0
ATRIAL FIBRILLATION / FLUTTER	Baseline						
	Absent	91	100.0				91 100.0
	Total	91	100.0				91 100.0
	Baseline						
CONDUCTION DISORDER	Absent	91	100.0				91 100.0
	Total	91	100.0				91 100.0
	Baseline						
	Absent	90	100.0				90 100.0
LEFT ANTERIOR HEMIBLOCK	Present			1	100.0		1 100.0
	Total	90	98.9	1	1.1		91 100.0
	Baseline						
	Absent	89	98.9	1	1.1		90 100.0
LEFT AXIAL DEVIATION	Present			1	100.0		1 100.0
	Total	89	97.8	2	2.2		91 100.0
	Baseline						
	Absent	90	100.0				90 100.0
LEFT BUNDLE BRANCH BLOCK	Present			1	100.0		1 100.0
	Total	90	98.9	1	1.1		91 100.0
	Baseline						
	Absent	90	100.0				90 100.0

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 85

E.C.G.: SHIF T TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Imipramine

		Last assessment						Total
		Absent			Present			
		No	Z	%	No	Z	%	
E.C.G. Abnormality	Baseline							
	Absent	90	98.9	1	1.1	91	100.0	
	Present							
	Total	90	98.9	1	1.1	91	100.0	
MYOCARDIAL ISCHEMIA	Baseline							
	Absent	88	100.0			88	100.0	
	Present			3	100.0	3	100.0	
	Total	88	96.7	3	3.3	91	100.0	
NON SPECIFIC ST-T WAVE CHANGES	Baseline							
	Absent	90	100.0			90	100.0	
	Present	1	100.0			1	100.0	
	Total	91	100.0			91	100.0	
OTHER	Baseline							
	Absent	90	100.0			90	100.0	
	Present			1	100.0	1	100.0	
	Total	90	98.9	1	1.1	91	100.0	
PREVIOUS MYOCARDIAL INFARCTION	Baseline							
	Absent	91	100.0			91	100.0	
	Present							
	Total	91	100.0			91	100.0	
RIGHT BUNDLE BRANCH BLOCK	Baseline							
	Absent	87	96.7	3	3.3	90	100.0	
	Present			1	100.0	1	100.0	
	Total							

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 TABLE No.: 85
 E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT
 AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Inipramine

E.C.G. Abnormality	Total	Last assessment							
		Absent		Present		Total			
		No	%	No	%	No	%		
RIGHT BUNDLE BRANCH BLOCK	87	95.6	4	4.4	91	100.0			
RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	90	100.0			90	100.0			
	1	100.0			1	100.0			
	91	100.0			91	100.0			
RIPOLARIZATION DISTURBANCES	91	100.0			91	100.0			
	91	100.0			91	100.0			
SINUS BRADYCARDIA (< 60)	86	98.9	1	1.1	87	100.0			
	3	75.0	1	25.0	4	100.0			
	89	97.8	2	2.2	91	100.0			
SINUS TACHYCARDIA (> 100)	81	92.0	7	8.0	88	100.0			
	1	33.3	2	66.7	3	100.0			
	82	90.1	9	9.9	91	100.0			
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	90	100.0			90	100.0			
	1	100.0			1	100.0			
	91	100.0			91	100.0			

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PHARMACIA CNS R&D
 REBOMETLINE - PROTOCOL 20124/015
 TABLE No.: 85
 E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT
 AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Placebo

	Last assessment									
	Absent			Present			Total			
	No	Z	%	No	Z	%	No	Z	%	
E.C.G. Abnormality	Baseline									
	Absent	94	98.9	1	1.1		95	100.0		
	Present									
	Total	94	98.9	1	1.1		95	100.0		
ATRIAL FIBRILLATION / FLUTTER	Baseline									
	Absent	95	100.0				95	100.0		
	Present									
	Total	95	100.0				95	100.0		
CONDUCTION DISORDER	Baseline									
	Absent	94	100.0				94	100.0		
	Present	1	100.0				1	100.0		
	Total	95	100.0				95	100.0		
LEFT ANTERIOR HEMIBLOCK	Baseline									
	Absent	94	98.9	1	1.1		95	100.0		
	Present									
	Total	94	98.9	1	1.1		95	100.0		
LEFT AXIAL DEVIATION	Baseline									
	Absent	94	100.0				94	100.0		
	Present									
	Total	94	100.0				94	100.0		
LEFT BUNDLE BRANCH BLOCK	Baseline									
	Absent	95	100.0				95	100.0		
	Present									
	Total	95	100.0				95	100.0		

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PHARMACIA CNS R&D
 REBORETTINE - PROTOCOL 20124/015
 TABLE No.: 85
 E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT
 AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Placebo

		Last assessment															
		Absent		Present		Total		Absent		Present		Total					
		No	Z	No	Z	No	Z	No	Z	No	Z	No	Z				
E.C.G. Abnormality	Baseline																
	Absent	94	100.0												94	100.0	
	Present	1	100.0												1	100.0	
	Total	95	100.0												95	100.0	
MYOCARDIAL ISCHEMIA	Baseline																
	Absent	94	100.0												94	100.0	
	Present	1	100.0												1	100.0	
	Total	95	100.0												95	100.0	
NON SPECIFIC ST-T WAVE CHANGES	Baseline																
	Absent	94	98.9	1	1.1										95	100.0	
	Present																
	Total	94	98.9	1	1.1										95	100.0	
OTHER	Baseline																
	Absent	95	100.0												95	100.0	
	Present	95	100.0												95	100.0	
	Total	95	100.0												95	100.0	
PREVIOUS MYOCARDIAL INFARCTION	Baseline																
	Absent	95	100.0												95	100.0	
	Present	95	100.0												95	100.0	
	Total	95	100.0												95	100.0	
RIGHT BUNDLE BRANCH BLOCK	Baseline																
	Absent	94	100.0												94	100.0	
	Present			1	100.0										1	100.0	
	Total	94	98.9	1	1.1										95	100.0	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
TABLE No.: 85

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Placebo

		Last assessment					
		Absent		Present		Total	
		No	Z	No	Z	No	Z
E.C.G. Abnormality RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	Baseline						
	Absent	95	100.0			95	100.0
	Total	95	100.0			95	100.0
RIPOLARIZATION DISTURBANCES	Baseline						
	Absent	93	100.0			93	100.0
	Present	1	50.0	1	50.0	2	100.0
Total	94	98.9	1	1.1	95	100.0	
SINUS BRADYCARDIA (< 60)	Baseline						
	Absent	89	96.7	3	3.3	92	100.0
	Present	1	33.3	2	66.7	3	100.0
Total	90	94.7	5	5.3	95	100.0	
SINUS TACHYCARDIA (> 100)	Baseline						
	Absent	94	100.0			94	100.0
	Present	1	100.0			1	100.0
Total	95	100.0			95	100.0	
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	Baseline						
	Absent	94	98.9	1	1.1	95	100.0
	Present						
Total	94	98.9	1	1.1	95	100.0	

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 REBOXETINE - PROTOCOL 20124/015
 TABLE No. 1 86
 E.C.G.: NUMBER AND PERCENTAGE OF E.C.G. ABNORMALITIES, BY ABNORMALITY GROUP, OBSERVED DURING THE STUDY
 BY ASSIGNED TREATMENT

Group of abnormalities	Imipramine						Placebo						Reboxetine					
	Screening		1-21 days		22-42 days		Screening		1-21 days		22-42 days		Screening		1-21 days		22-42 days	
	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Evaluated Pt.	91	100.0	80	100.0	75	100.0	95	100.0	86	100.0	82	100.0	91	100.0	86	100.0	79	100.0
Rhythm disorders	7	7.7	10	12.5	8	10.7	4	4.2	8	9.3	7	8.5	8	8.8	6	7.0	5	6.3
Conduction disorders	4	4.4	7	8.8	5	6.7	3	3.2	3	3.5	2	2.4	1	1.1	2	2.3		
Ischemic signs	4	4.4	2	2.5	2	2.7	3	3.2	3	3.5			5	5.5	2	2.3	3	3.8
Other disorders	1	1.1	3	3.8			1	1.1					3	3.3	3	3.5	3	3.8

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
TABLE No.: 57

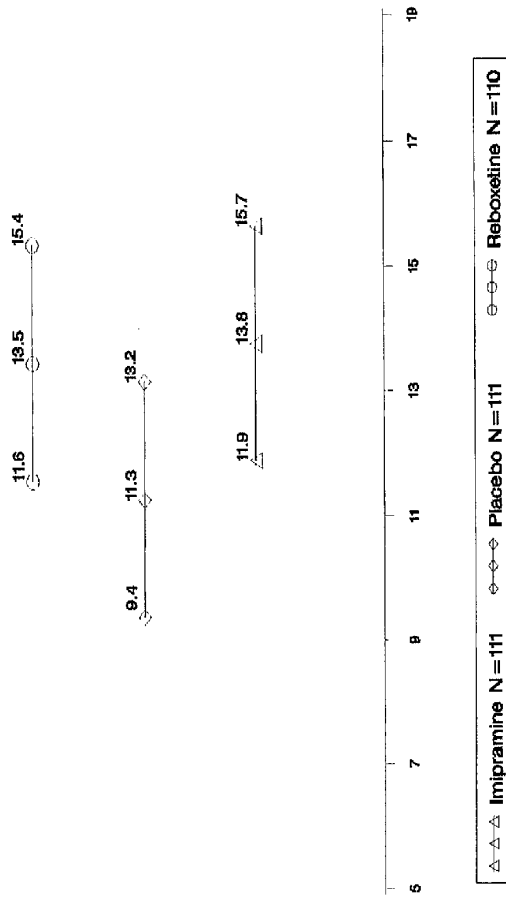
E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES, BY ABNORMALITY GROUP, AT LAST ASSESSMENT AS COMPARED TO PRETREATMENT EVALUATION, BY ASSIGNED TREATMENT

E.C.G. Abnormality / Baseline	Last assessment																							
	Imipramine												Reboxetine											
	Absent						Present						Absent						Present					
	No	Z	%	Total	No	Z	%	No	Z	%	Total	No	Z	%	No	Z	%	Total	No	Z	%	Total		
Rhythm disorders	Absent	76	90.5	8	9.5	84	100	86	94.5	5	5.5	91	100	80	96.4	3	3.6	83	100					
	Present	4	57.1	3	42.9	7	100	2	50.0	2	50.0	4	100	5	62.5	3	37.5	8	100					
	Total	80	87.9	11	12.1	91	100	88	92.6	7	7.4	95	100	85	93.4	6	6.6	91	100					
Conduction disorders	Absent	84	96.6	3	3.4	87	100	92	100				92	100	90	100								
	Present			4	100	4	100														1	100	1	100
	Total	84	92.3	7	7.7	91	100	92	96.8	3	3.2	95	100	90	98.9	1	1.1	91	100					
Ischemic signs	Absent	87	100			87	100	91	98.9	1	1.1	92	100	86	100									
	Present	1	25.0	3	75.0	4	100	2	66.7	1	33.3	3	100	2	40.0	3	60.0	5	100					
	Total	88	96.7	3	3.3	91	100	93	97.9	2	2.1	95	100	88	96.7	3	3.3	91	100					
Other disorders	Absent	90	100			90	100	94	100			94	100	88	100									
	Present			1	100	1	100	1	100			1	100							3	100	3	100	
	Total	90	98.9	1	1.1	91	100	95	100			95	100	88	96.7	3	3.3	91	100					

FIGURES

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
**MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT
 POINT ESTIMATES AND CONFIDENCE INTERVALS**
 Figure No.: 1

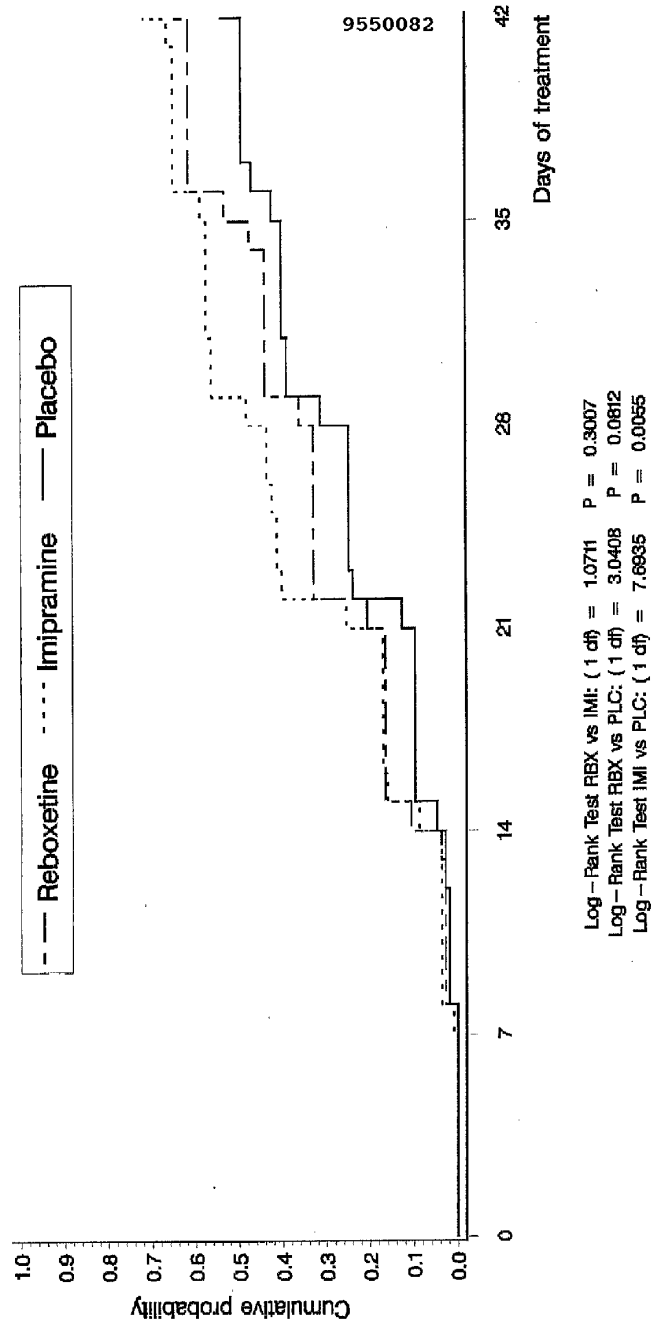


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REBOXETINE - PROTOCOL 20124/015
CUMULATIVE PROBABILITY OF 50% DECREASE IN HAMD TOTAL SCORE

Figure No.: 2



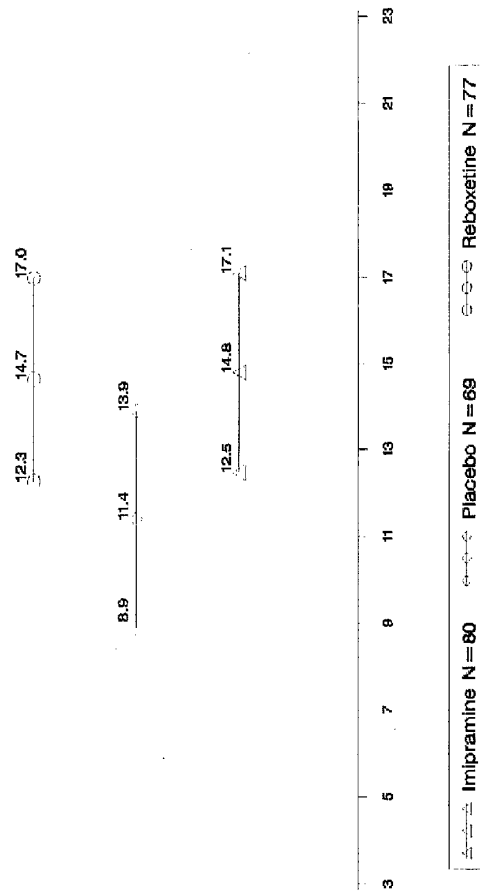
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PHARMACIA CNS R&D

**REBOXETINE – PROTOCOL 2012/4/015
SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE
MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT
POINT ESTIMATES AND 95% CONFIDENCE INTERVALS**

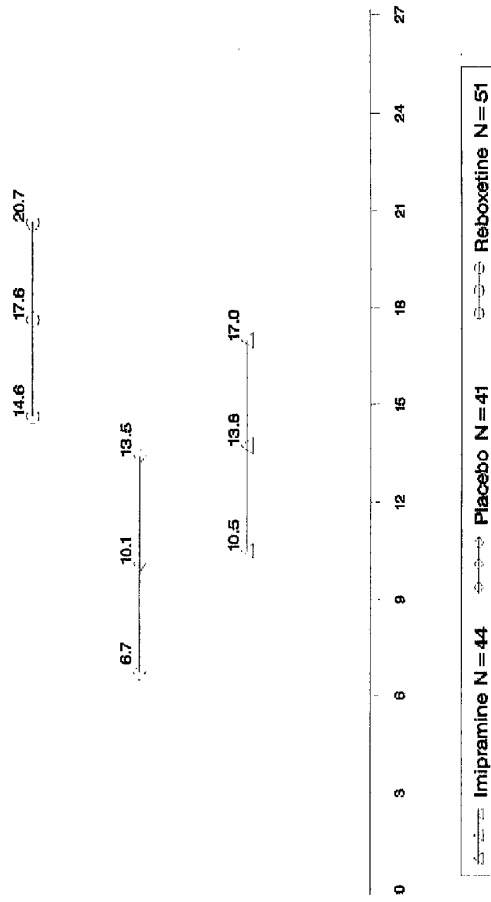
Figure No.: 3



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PHARMACIA CNS R&D
REBOXETINE – PROTOCOL 20124/015
MELANCHOLIC PATIENTS MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT
POINT ESTIMATES AND 95% CONFIDENCE INTERVALS

Figure No.: 4



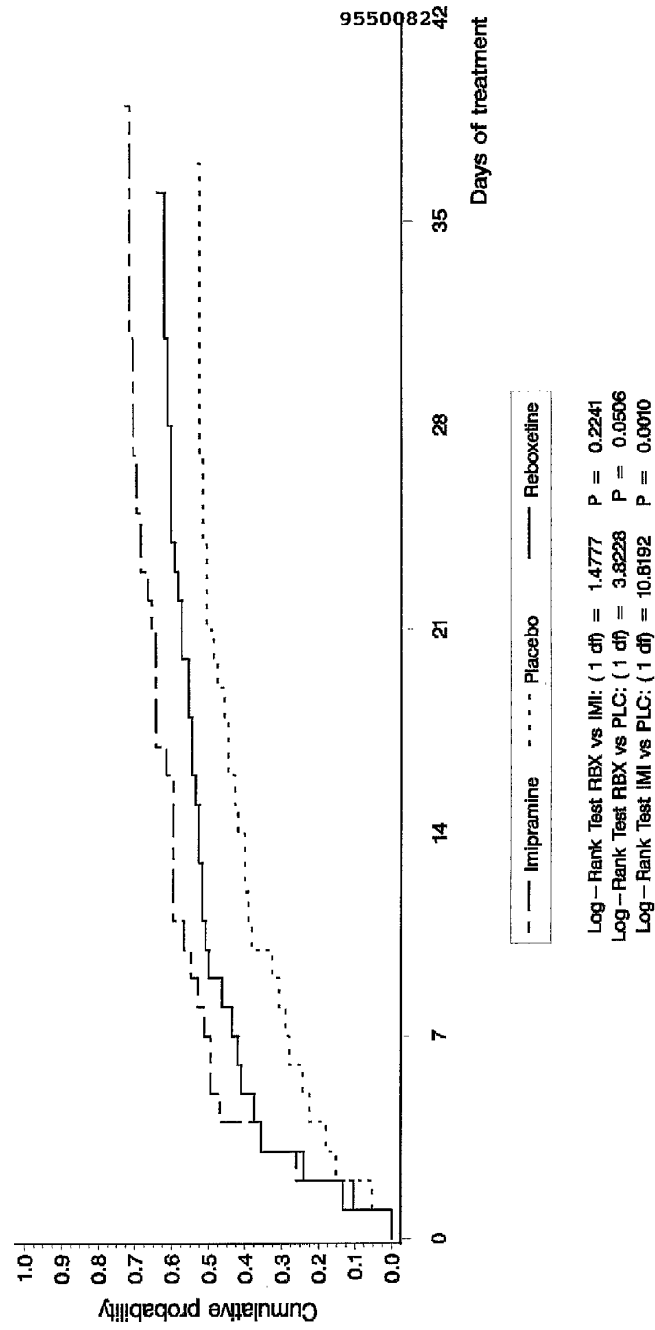
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATMENT

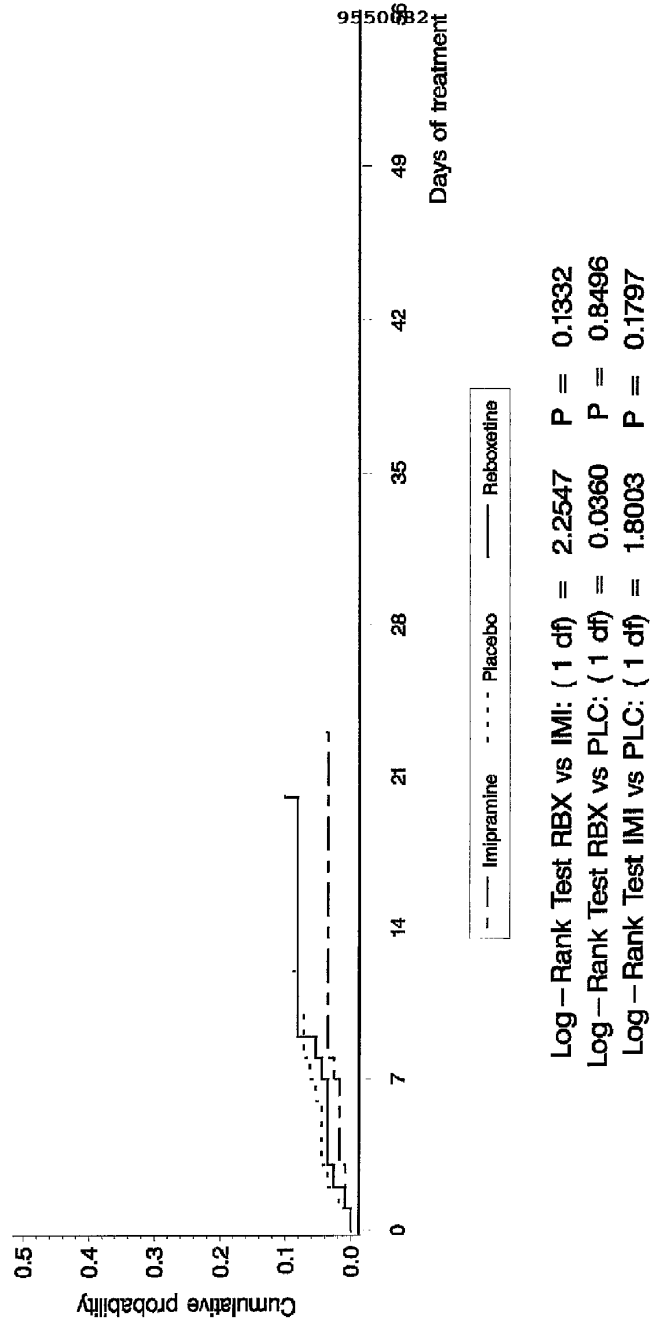
Figure No.: 5



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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

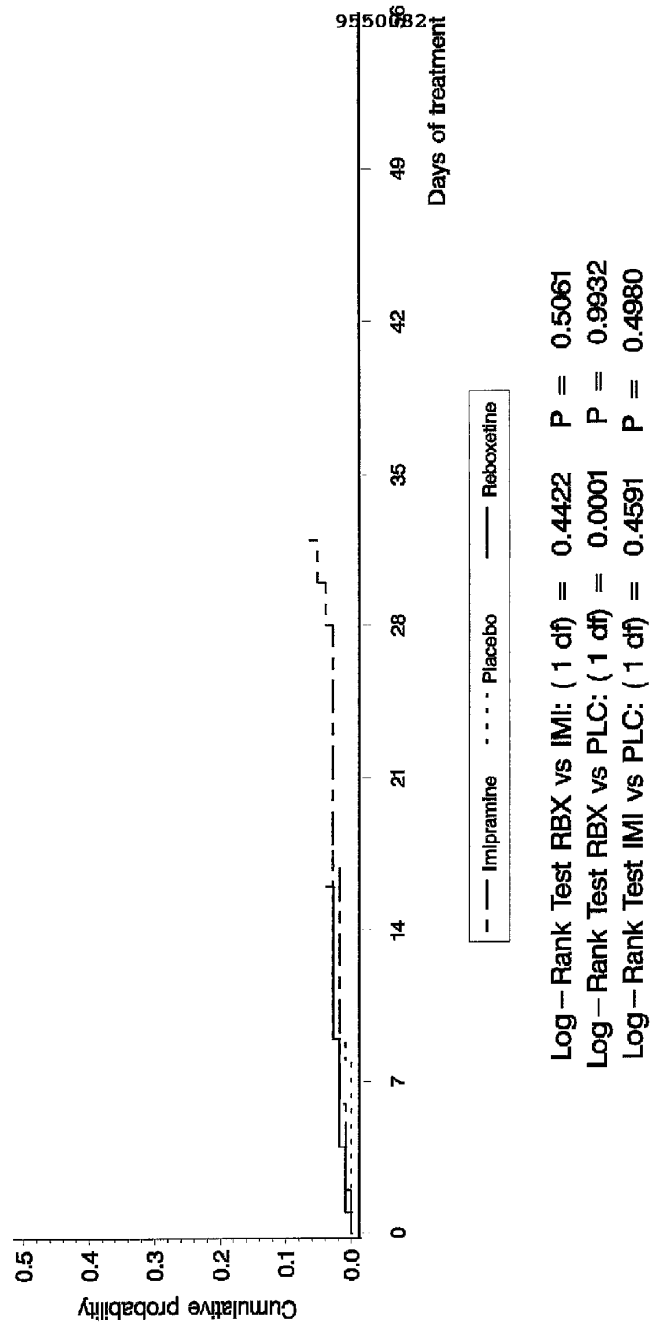
Figure No.: 6



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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING ASTHENIA / FATIGUE

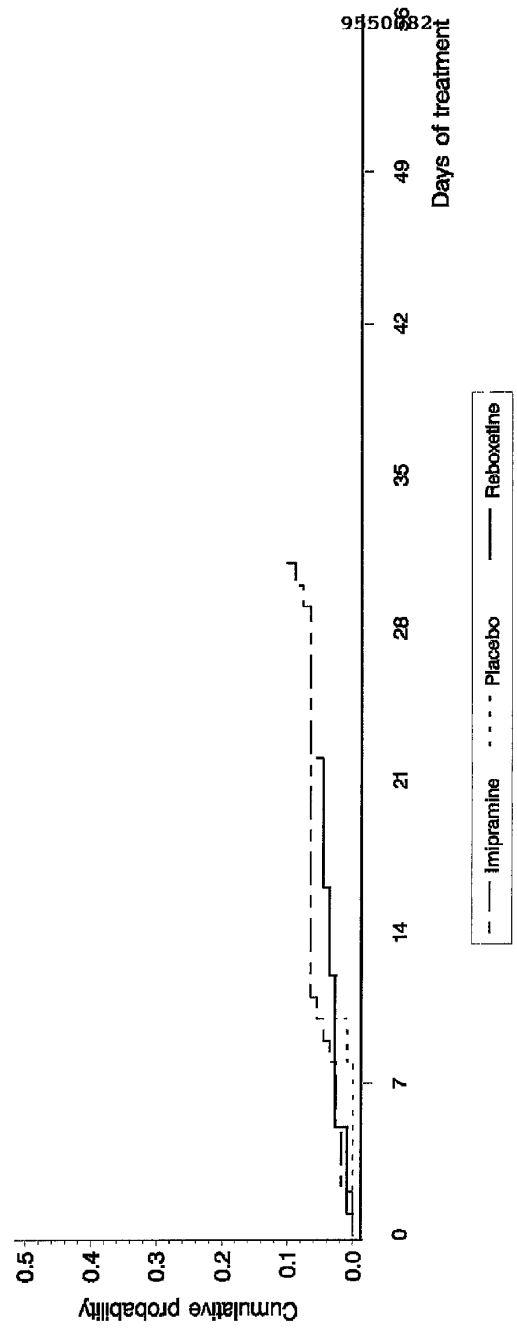
Figure No.: 7



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 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING BLURRED VISION

Figure No.: 8



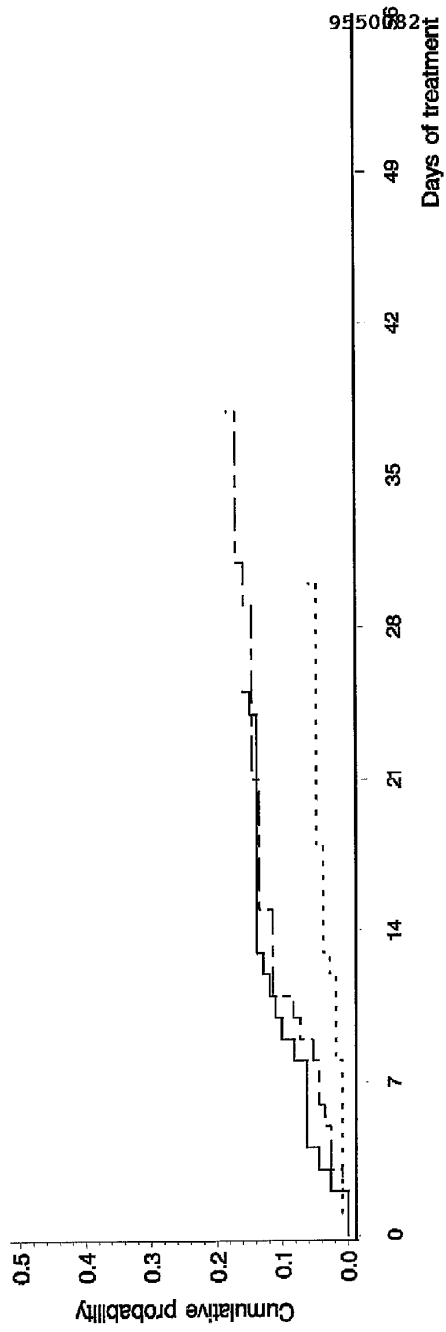
Log-Rank Test RBX vs IMI: (1 df) = 1.1657 P = 0.2803
 Log-Rank Test RBX vs PLC: (1 df) = 1.0249 P = 0.3114
 Log-Rank Test IMI vs PLC: (1 df) = 4.1156 P = 0.0425

425

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/016
CUMULATIVE RISK OF DEVELOPING CONSTIPATION

Figure No.: 9



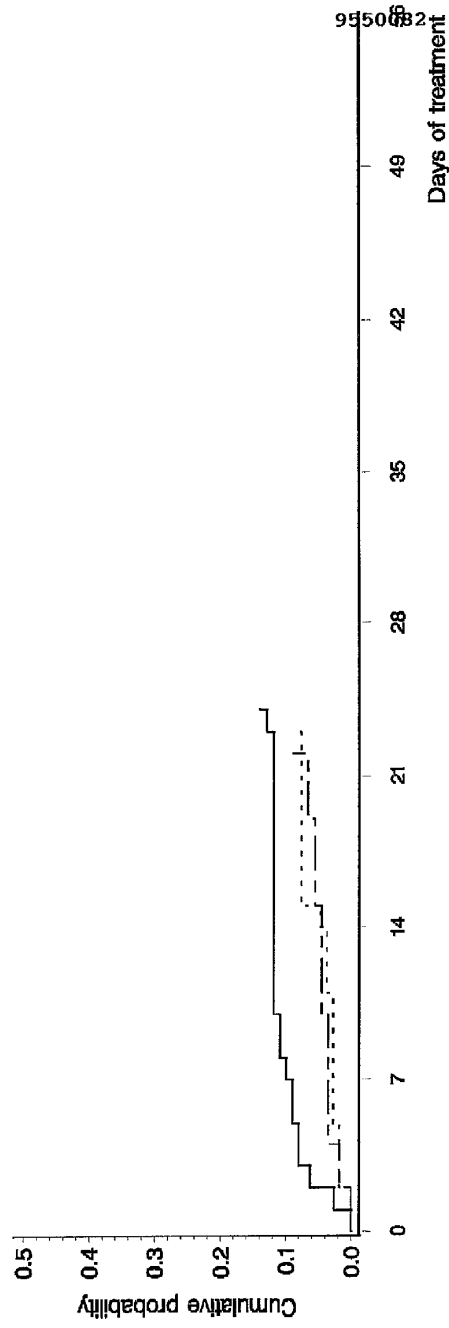
Log-Rank Test RBX vs IMI: (1 df) = 0.0529 P = 0.8182
 Log-Rank Test RBX vs PLC: (1 df) = 5.8558 P = 0.0155
 Log-Rank Test IMI vs PLC: (1 df) = 7.2476 P = 0.0071

525

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING HEADACHE / MIGRAINE

Figure No.: 10

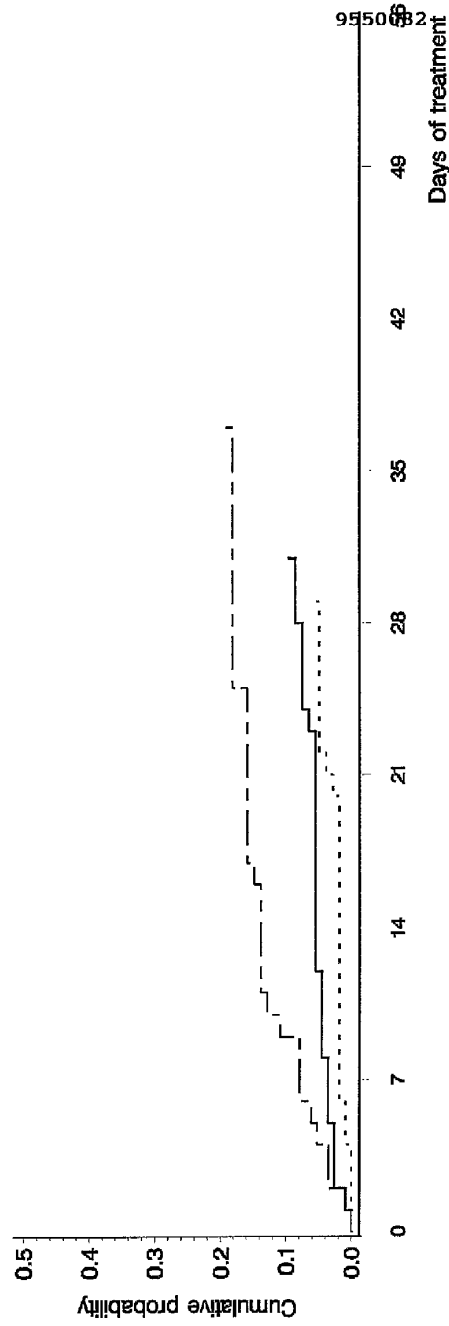


Log – Rank Test RBX vs IMI: (1 df) = 1.7542 P = 0.1853
 Log – Rank Test RBX vs PLC: (1 df) = 1.7892 P = 0.1810
 Log – Rank Test IMI vs PLC: (1 df) = 0.0023 P = 0.9619

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING HYPOTENSION AND RELATED SYMPTOMS

Figure No.: 11

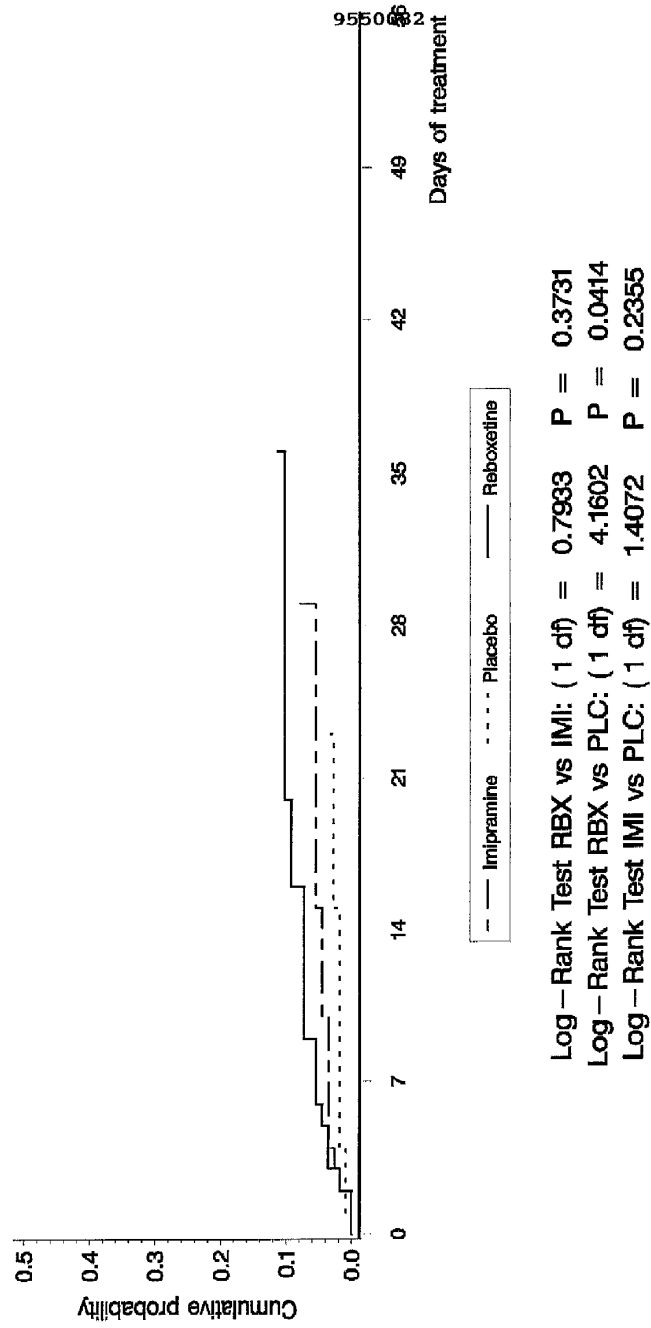


Log-Rank Test RBX vs IMI: (1 df) = 4.1630 P = 0.0413
 Log-Rank Test RBX vs PLC: (1 df) = 1.0066 P = 0.3157
 Log-Rank Test IMI vs PLC: (1 df) = 8.9049 P = 0.0028

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
 CUMULATIVE RISK OF DEVELOPING INSOMNIA

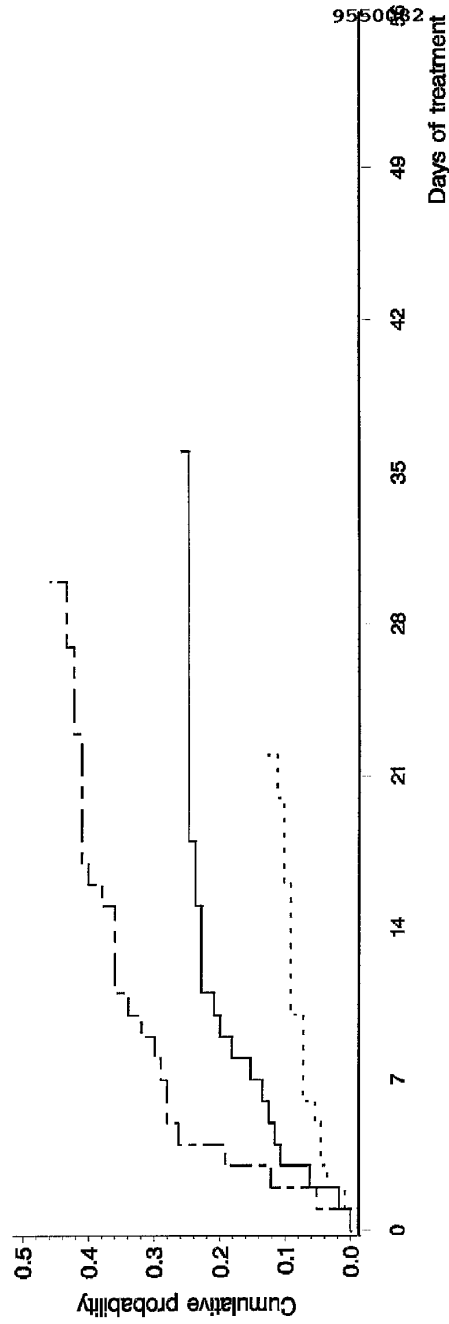
Figure No.: 12



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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/016
CUMULATIVE RISK OF DEVELOPING MOUTH DRY

Figure No.: 13

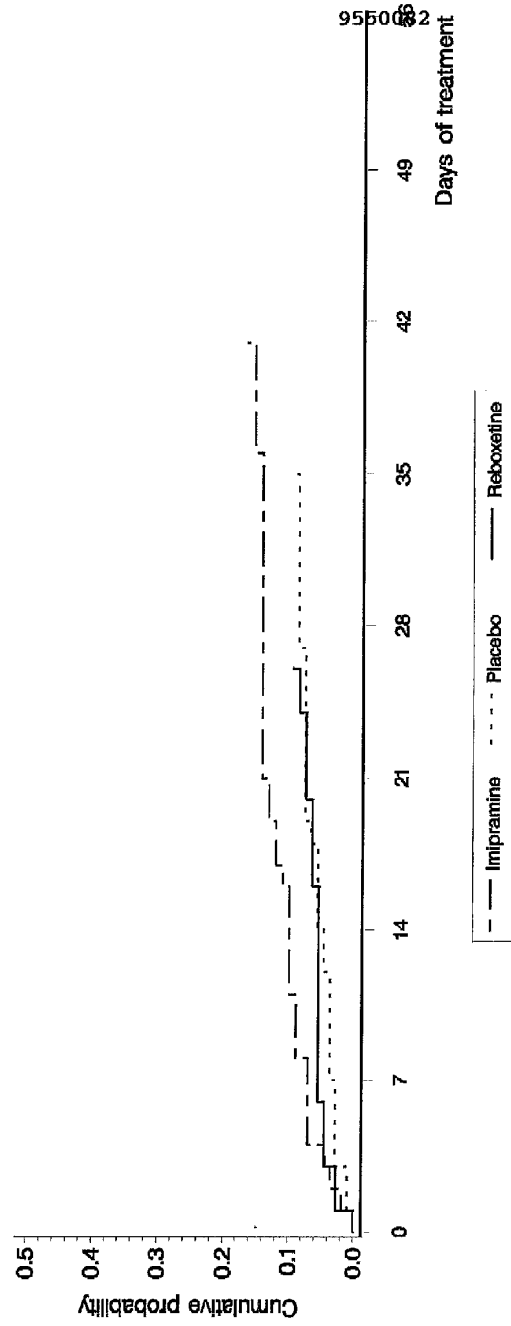


Log-Rank Test RBX vs IMI: (1 df) = 9.0046 P = 0.0027
 Log-Rank Test RBX vs PLC: (1 df) = 5.6707 P = 0.0173
 Log-Rank Test IMI vs PLC: (1 df) = 27.5434 P = 0.0001

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING NAUSEA AND RELATED SYMPTOMS

Figure No.: 14

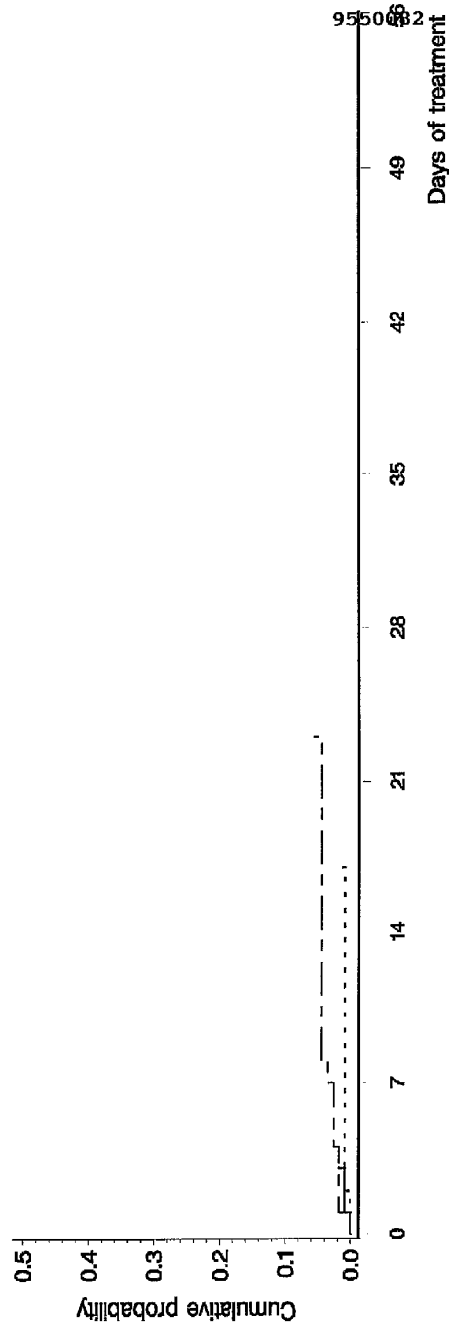


Log – Rank Test RBX vs IMI: (1 df) = 2.0986 P = 0.1474
 Log – Rank Test RBX vs PLC: (1 df) = 0.0000 P = 0.9963
 Log – Rank Test IMI vs PLC: (1 df) = 2.1983 P = 0.1382

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING PARAESTHESIA

Figure No.: 15

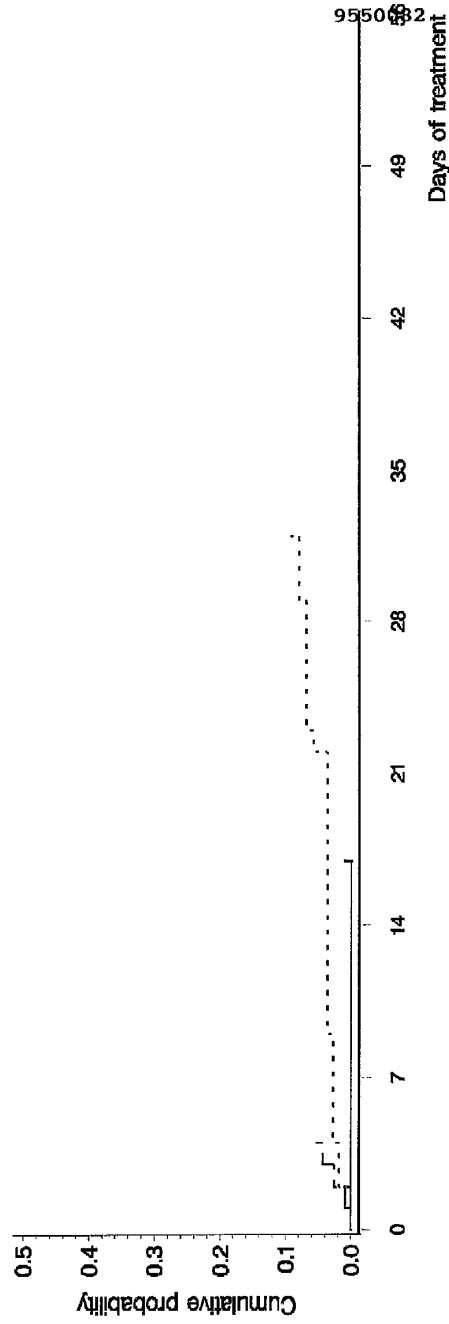


Log-Rank Test RBX vs IMI: (1 df) = 2.0112 P = 0.1561
 Log-Rank Test RBX vs PLC: (1 df) = 0.0000 P = 0.9945
 Log-Rank Test IMI vs PLC: (1 df) = 2.0573 P = 0.1515

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING SOMNOLENCE

Figure No.: 16

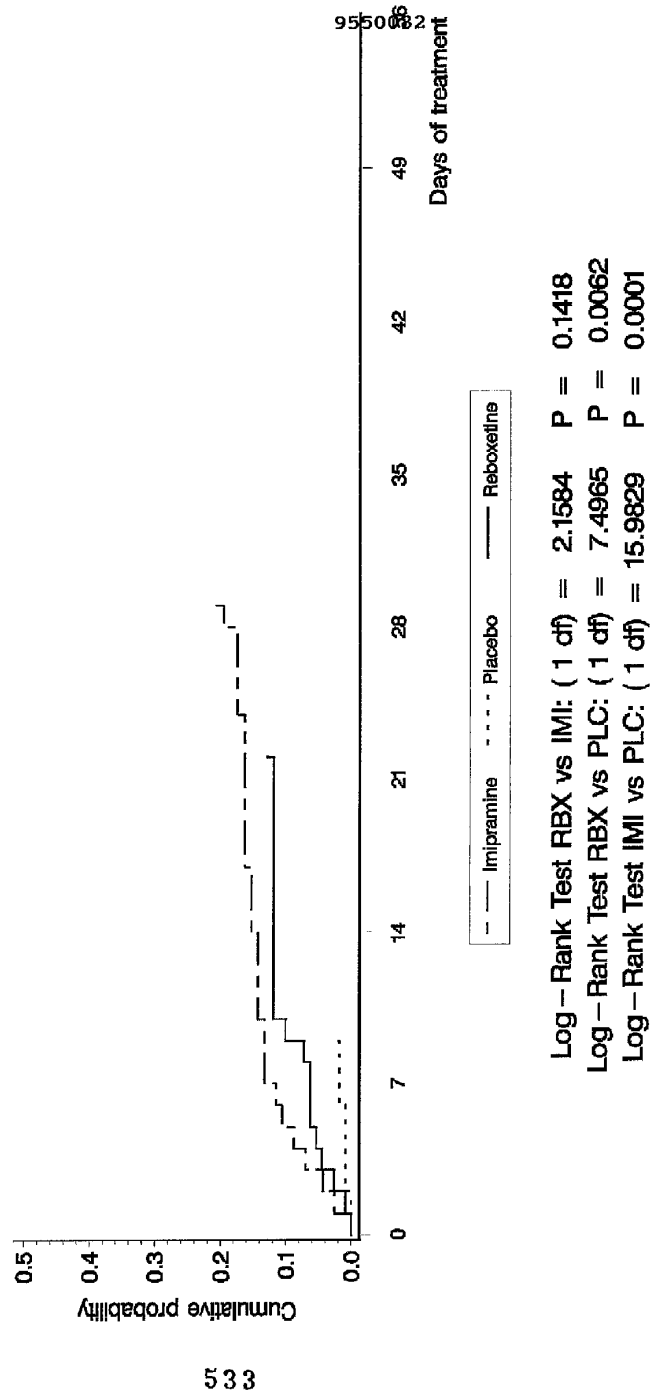


Log-Rank Test RBX vs IMI: (1 df) = 3.6284 P = 0.0568
 Log-Rank Test RBX vs PLC: (1 df) = 6.8579 P = 0.0088
 Log-Rank Test IMI vs PLC: (1 df) = 0.5682 P = 0.4510

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PHARMACIA CNS R&D
REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING SWEATING INCREASED

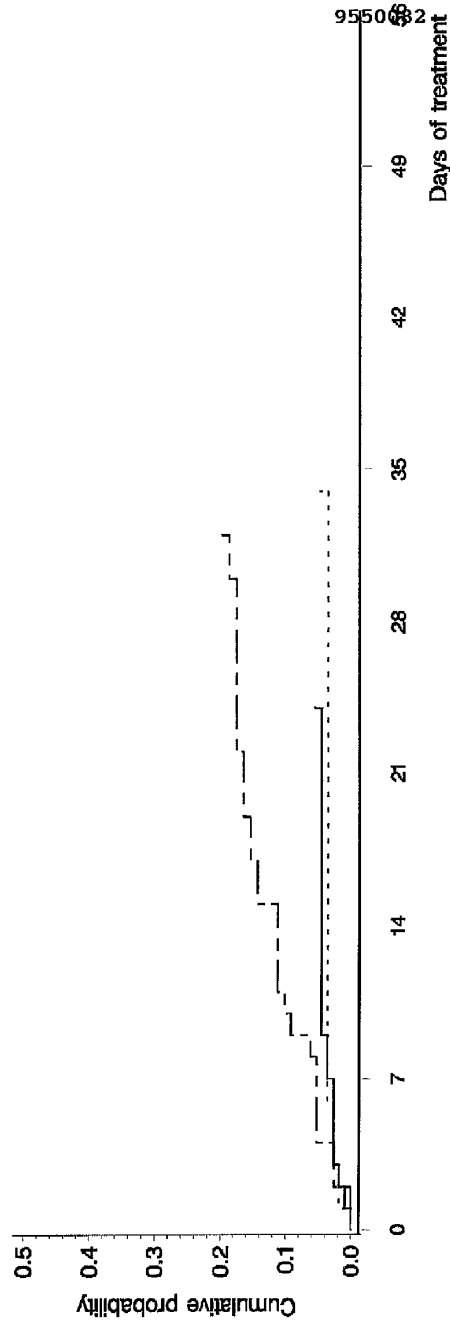
Figure No.: 17



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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL_20124/015
CUMULATIVE RISK OF DEVELOPING TREMOR

Figure No.: 18

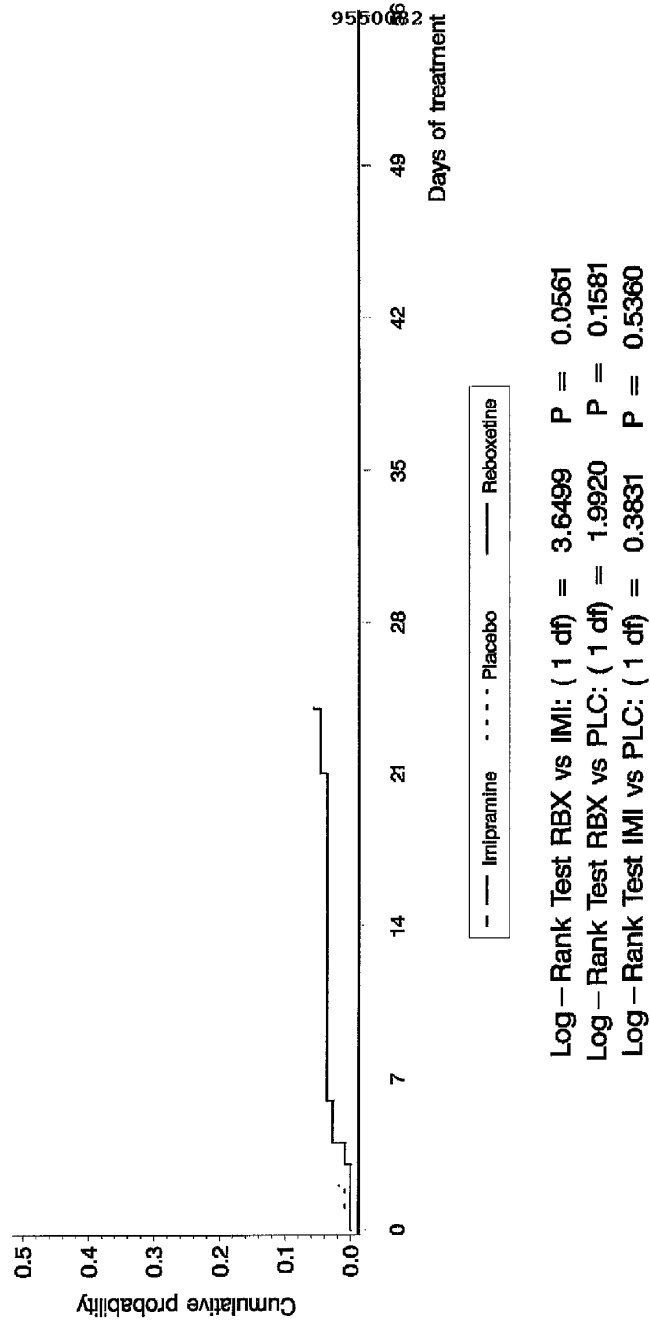


Log-Rank Test RBX vs IMI: (1 df) = 8.6796 P = 0.0032
 Log-Rank Test RBX vs PLC: (1 df) = 0.0863 P = 0.7690
 Log-Rank Test IMI vs PLC: (1 df) = 10.2165 P = 0.0014

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING URINARY HESITANCY / RETENTION

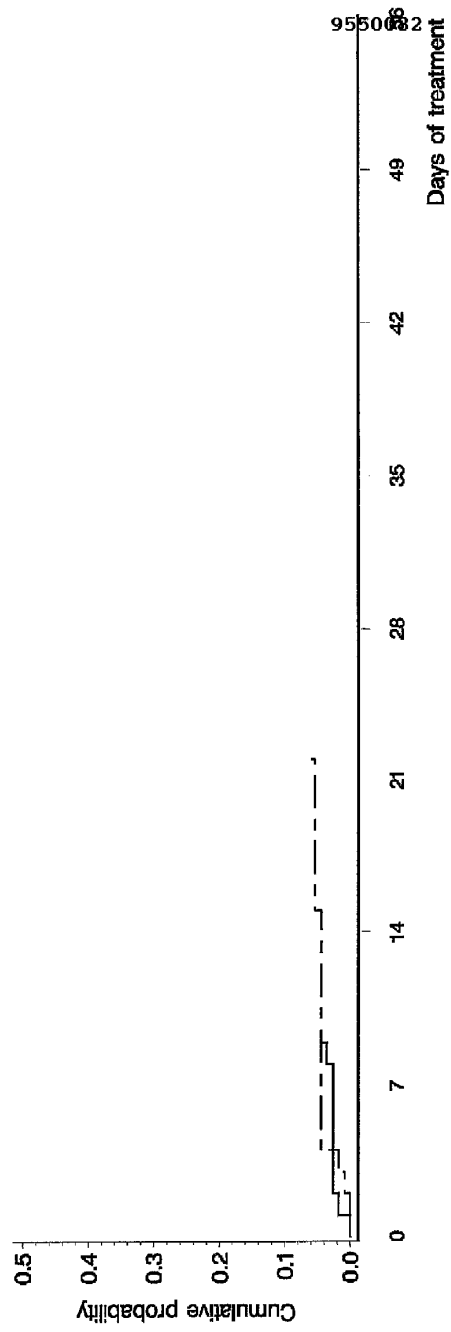
Figure No.: 19



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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/015
CUMULATIVE RISK OF DEVELOPING VERTIGO

Figure No.: 20



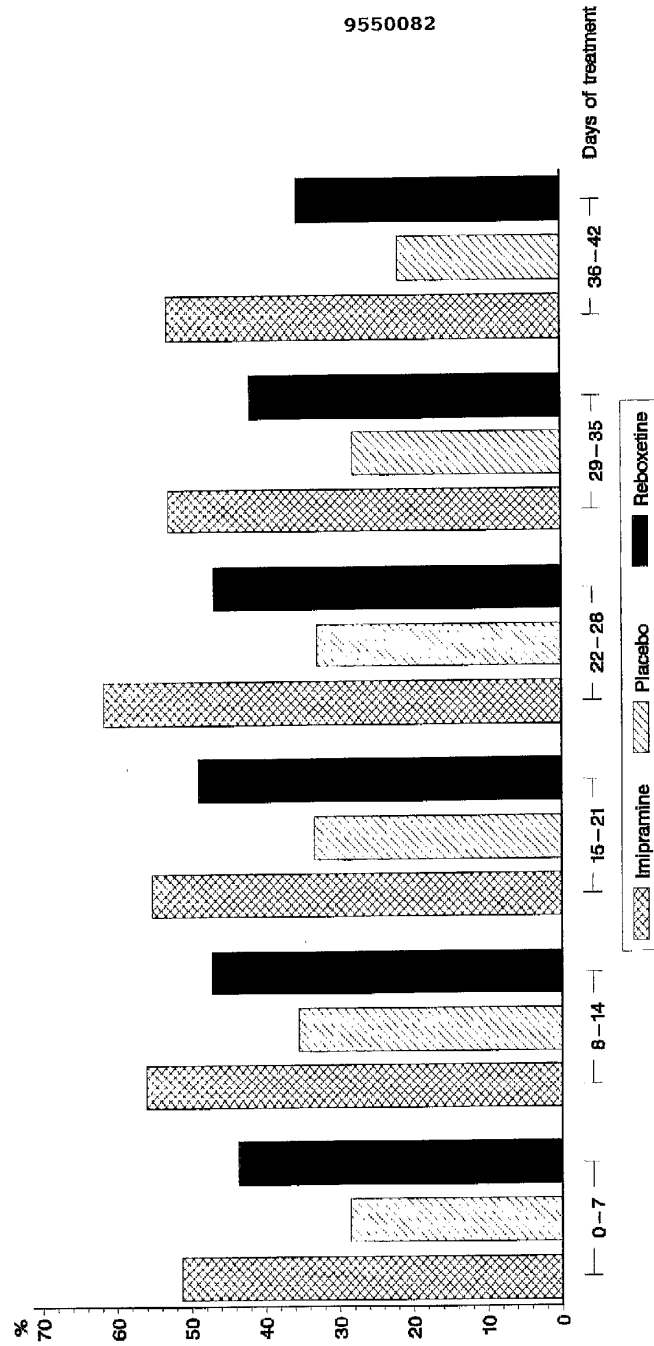
— Imipramine ···· Placebo — Reboxetine

Log – Rank Test RBX vs IMI: (1 df) = 0.3223 P = 0.5702
 Log – Rank Test RBX vs PLC: (1 df) = 5.0571 P = 0.0245
 Log – Rank Test IMI vs PLC: (1 df) = 7.1125 P = 0.0077

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REBOXETINE – PROTOCOL 20124/015
PERCENTAGE OF PATIENTS WITH AT LEAST ONE ADVERSE EVENT ON EXPOSED ACCORDING TO TIME INTERVAL

Figure No.: 21



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Document 9550082

12. APPENDICES

Pharmacia

Document 9550082

12.1 Study Information

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Document 9550082

12.1.1 PROTOCOLS* AND PROTOCOL AMENDMENTS

*Copy of the final protocol, as well as the modified protocol used in the Canadian centre.

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CNS LINE

AMENDMENT 1 to the
REBOXETINE PROTOCOL 20124/015

The paragraph 9.1 will be as follow:

9.1. Pre-treatment period

Patients will be checked for eligibility according to the inclusion and exclusion criteria. A washout period of 4-7 days (14 days in case of MAOI administration, and 3-4 weeks in case of previous fluoxetine treatment) will then be undertaken, during which only chloral hydrate (0.5 - 1.0 g) as sleep inducer on p.r.n. basis will be allowed. Informed consent will be obtained from each patient and/or next of kin.

Eligible patients will be then randomized to one of the three treatment groups and will undergo baseline assessments.

Information on patients screened for the study and found not to be eligible will be collected in the appropriate form (screening form, enclosure 5).

Signatures:

Investigator _____

Study Monitor _____

Product Leader John Payne

Line Medical Head Edoardo Debin

Biostatisticians Ricardo Spezia

541

30184/015

Date: January 16, 1991

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1400X

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EBRAMONT GROUP
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AMENDMENT 2 to the
REBOXETINE PROTOCOL 20124/015
AUSTRALIA

The paragraph 9.1 will be as follow:

Patients will be checked for eligibility according to the inclusion and exclusion criteria. A washout period of 4-7 days (14 days in case of MAOI administration and 3 - 4 weeks in case of previous fluoxetine treatment) will then be undertaken, during which only sleep inducer (see 9.2.5) will be allowed. Informed consent will be obtained from each patient and/or next of kin. Eligible patients will be then randomized to one of the three treatment groups and will undergo baseline assessments. Information on patients screened for the study and found not to be eligible will be collected in the appropriate screening form.

The paragraph 9.2.5 will be as follow:

No concomitant medications other than hypnotic on p.r.n. basis are allowed at entry into the study. Concomitant medication should be avoided throughout the study. In case of events arising during the course of the study nonpsychotropic medications which are considered necessary for the patient's welfare may be administered and will not be considered violation to the protocol. The drugs, dosage and frequency of administration will be recorded. Short acting benzodiazepines (for instance temazepam 10mg tablet) as sleep inducer on p.r.n. basis at bed-time are allowed.

Signatures:

Investigator _____

Study Monitor _____

Product Leader Jill Jane

Line Medical Head Maricela Dubin

542

20124/015 Australia

Date: March 26, 1991

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AMENDMENT 2 to the
REBOXETINE PROTOCOL 20124/015
FRANCE

1) The paragraph 15.2 will be as follows :

Before entering the study each patient will receive an explanation of the nature, duration and purpose of the study and the action of the compound in such a manner that the patient is aware of the potential risks, inconveniences or adverse effects that may occur and can express his/her informed consent to participate.

The consent form (enclosure 3) will be signed by the patient and by the investigator. If the patient is not able to give his/her consent, the signature by the next of kin will testify that full informations was given to the patient.

2) Consent Form
(to see the next page)

Signatures:

Investigator _____

Study Monitor _____

Product Leader *Christophe Jaurès* _____

Line Medical Head *Christine Dubini* _____

Biostatisticians _____

543

80184/015

Date: January 16, 2001

9550082

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AMENDMENT 2 to the
REBOXETINE PROTOCOL 20124/015
GERMANY and CANADA

The statement "High risk of suicide" in the paragraph
6.3 Exclusion criteria will be as follows:

- High risk of suicide defined as a score "3" or "4" in the
Hamilton Depression Rating Scale item # 3 "Suicide".

Signatures:

Investigator _____

Study Monitor _____

Product Leader John Jones

Line Medical Head Adrian Dubois

Biostatistician John Jones

544

20124/015

Date: November 15, 1991

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R&D - C.N.S. LINE

COMPOUND: REBOXETINE

PROTOCOL No. : 20124/015

VERSION : Final: 19.09.1990

PHASE : III

TITLE : Multicenter, multinational double-blind study of the activity and tolerability of reboxetine vs imipramine and placebo in patients suffering from Major Depressive Episodes.

INVESTIGATORS : See enclosure 1

PRODUCT LEADER : Marek Jarema
Farmitalia Carlo Erba
R&D, CNS Dpt
Via Carlo Imbonati, 24
20159 Milano
Phone: 039-2-69952749

STUDY MONITOR : See enclosure 16

DATA MANAGEMENT : Biostatistics and
CENTER Data Management FICE Milan

This protocol contains strictly confidential information which is not to be communicated or published unless previously authorized by Farmitalia Carlo Erba R&D.

20124/015

Date: September 19, 1990

FARMITALIA CARLO ERBA
 ERBAMONT GROUP
 CNS LINE

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TABLE OF CONTENTS

1.0	PROTOCOL SUMMARY	Page	1
2.0	INTRODUCTION	"	1
3.0	RATIONALE	"	4
4.0	OBJECTIVES	"	4
5.0	DESIGN	"	4
5.1	Description	"	4
5.2	Number of subjects proposed	"	4
5.3	Logistics	"	5
6.0	STUDY POPULATION	"	5
6.1	Source of Subjects	"	5
6.2	Inclusion Criteria	"	5
6.3	Exclusion Criteria	"	5
6.4	Identification of subjects	"	6
7.0	RANDOMIZATION AND REGISTRATION PROCEDURES	"	6
8.0	EXPERIMENTAL TREATMENTS	"	6
8.1	Test preparation	"	6
8.2	Labelling	"	7
8.3	Packaging	"	7
8.4	Drug supplies storage	"	7
8.5	Dispensing, use and disposition of test drugs during and at the end of the study	"	8
9.0	STUDY CONDUCT	"	8
9.1	Pre-treatment period	"	8
9.2	Treatment period	"	8
9.2.1	Dose/route of administration/ treatment schedule	"	8
9.2.2	Duration of treatment	"	9
9.2.3	Indications for early termination of test therapy	"	9
9.2.4	Dropouts/Replacement of subjects	"	9
9.2.5	Concomitant therapy	"	9
9.2.6	Indications for opening the code	"	10
9.3	Follow-up	"	10
9.4	Study timetable	"	10
10.0	EFFICACY ASSESSMENTS	"	10
10.1	Variables to be measured for efficacy assessment	"	10

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10.2	Efficacy definition	"	11
10.3	Cognitive function evaluability	"	11
10.4	Criteria for subject evaluability	"	11
11.0	SAFETY ASSESSMENT	"	11
11.1	Variables to be measured for safety assessment	"	11
11.2	Criteria for subject evaluability	"	12
12.0	ADVERSE EVENTS	"	12
13.0	EVALUATION SCHEDULE	"	13
14.0	STATISTICAL CONSIDERATIONS	"	13
14.1	Sample size	"	13
14.2	Statistical analysis	"	14
15.0	ETHICAL ASPECTS	"	15
15.1	Ethical committee	"	15
15.2	Informed consent	"	16
16.0	PROTOCOL AMENDMENTS	"	16
17.0	STUDY MONITORING	"	16
18.0	DRUG SUPPLY AND DRUG INVENTORY	"	17
19.0	ADMINISTRATIVE ASPECTS	"	17
19.1	Insurance policy	"	17
19.2	Curriculum vitae	"	17
19.3	Data collection in the Case Record Form	"	17
19.4	Use and publications of the data obtained from the study	"	18
20.0	STUDY REPORT	"	18
20.1	Clinical Study Final Report	"	18
20.2	Use and publication of the study result	"	18
21.0	END OF THE STUDY	"	18
22.0	STUDY COORDINATION	"	18
23.0	REFERENCES	"	19
24.0	SIGNATURES	"	19

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1.0 PROTOCOL SUMMARY

The study, aimed at the evaluation of the efficacy and tolerability of reboxetine in comparison with imipramine and placebo in patients suffering from Major Depressive Episodes, will be carried out on a multinational basis, according to a double-blind parallel group design, in 330 patients. After an initial washout period of 1-2 weeks, patients will receive either reboxetine or imipramine or placebo, administered according to a fixed-flexible dose regimen, for 6 weeks. Efficacy (Clinical Global Impression, Hamilton Depression Rating Scale, Montgomery-Asberg Depression Rating Scale, Patient Global Impression), and tolerability (newly observed signs and symptoms, lab tests and ECG) will be assessed every 1-2 weeks. At the end of the 6-week treatment period a long-term follow-up may be undertaken.

2.0 INTRODUCTION

Reboxetine (FCE 20124 or RS, RS 2-[α -(2-ethoxy-phenoxy)benzyl] morpholine methanesulphonate) is a chemically new compound highly potent in pharmacological and biochemical tests predictive of antidepressant effectiveness: reserpine antagonism, norepinephrine reuptake inhibition, REM sleep latency increase. In addition reboxetine has been found to be able to prevent clonidine effects in rodents after single oral administration, in contrast with what observed following tricyclic monoamine uptake inhibitors, which were found to be active only upon repeated doses: these results indicate that the compound is able to decrease the sensitivity of α_2 noradrenergic receptors, one of the biochemical correlates of chronic antidepressant treatment, after single oral dose: therefore it may be expected to exert antidepressant effectiveness of faster onset with respect to available antidepressants in patients (1).

In phase I studies (2, 3) single doses of 0.5 - 5 mg of compound, were administered orally to healthy volunteers. After 5 mg orthostatic hypotension, accompanied by tachycardia and by subjective symptomatology consistent with the disturbed circulatory regulation was observed.

In these studies single doses of 1 & 3 mg of the compound showed dose-dependent CNS effects with EEG modifications (decreased power of theta and fast-beta waves in the fronto-central derivative), performance improvement (peg-board test) and growth hormone increase, the latter reportedly sensitive to hypothalamic noradrenergic stimulation by norepinephrine reuptake inhibitors.

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The comparison with the positive control, imipramine 75 mg, associated to similar EEG modifications in the fronto-central derivative, to modifications indicative of sedative activity in the occipito-temporal derivative and to deterioration of the Pauli performance test, in the absence of growth hormone modifications, indicate that reboxetine does not possess the marked sedative activity of imipramine, but rather psychostimulating properties. After all treatment standing heart rate increase and salivation decrease was apparent. No other modifications of tolerability parameters were observed.

The pharmacokinetics of the compound were evaluated in the above mentioned studies as well as after administration of 2 mg 14C-FCE 20124 to 3 healthy volunteers (4). Most of the radioactivity circulating in plasma (73% in terms of AUC) was accounted for by unchanged reboxetine; the average peak levels were observed at 2 h, with remarkably stable levels 1-6 hours after administration; its plasma half-life was estimated as 13.2 h, slightly lower than that of total radioactivity.

In addition the autonomic effects of the compound have been evaluated in a study carried out in 16 healthy volunteers according to a double-blind, latin square experimental design. Single doses of reboxetine 1, 2 & 4 mg, desipramine 25, 50 and 100 mg and placebo were administered at weekly intervals. Both reboxetine and desipramine were found to be similarly active in reducing salivation and antagonizing carbachol-evoked sweating, activities consistent with anticholinergic properties, and in increasing heart rate (consistent with muscarinic receptor blockade and/or noradrenergic stimulation); reboxetine, but not desipramine, was found to increase resting pupil diameter (consistent with muscarinic receptor blockade and/or α -stimulation) and to antagonize light evoked-miosis (consistent with anticholinergic activity).

Neither reboxetine nor desipramine were found to modify phenylephrine evoked sweating (no evidence of α -adrenoceptor blockade); following reboxetine a reduction of phenylephrine-evoked mydriasis was apparent, possibly due to a "ceiling effect" (due to the mydriatic effect of reboxetine) rather than α -adrenoceptor blockade. No evidence of noradrenaline-uptake blockade could be observed, since noradrenaline failed to evoke measurable pupillary response.

On the basis of the results of the phase I studies, a 6-center early phase II study was carried out aimed at assessing tolerability and activity of progressively increased doses of reboxetine, administered over a 4-week period to hospitalized patients suffering from Major Depressive Disorders (5).

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Ninety-eight patients were admitted to the study to be treated with maximum reboxetine daily doses of 4 mg (29 pts), 6 mg (27 pts), 8 mg (18 pts), 10 mg (12 pts) and 12 mg (12 pts). Treatment was discontinued in 4 patients in the 4 mg group due to deterioration of the clinical picture (with a manic syndrome in one case); in 2 patients of the 6 mg group due to the development of a manic episode; in one patient of the 6 mg group due to a convulsive episode, under associated treatment with levomepromazine. Dosage decrease was almost only present in the 12 mg group where in 5/12 cases, due to hypotension and tachycardia, the daily dose was decreased to 10 mg until completion of the treatment period.

The rating scales applied showed dose related improvement of the clinical picture both as average changes vs basal conditions as well as frequencies of relevant modifications (defined as 50% decrease of HAMD) up to the 10 mg/day dose, whereas slight deterioration, concomitant to the intolerance signs/symptoms, was observed in the highest dose group.

The compound was well tolerated when administered at doses up to 10 mg/day, as shown by newly observed signs and symptoms, mainly of mild to moderate severity and transient, and by vital signs and lab tests assessments, ECG included.

A double blind parallel group study was subsequently carried out in 10 centers (Hungary, Italy, France and Latin America) in 258 patients hospitalized due to a Major Depressive Episode. The experimental treatment had to be administered for 4 weeks, with maximum doses of 8 mg reboxetine (RBX) or 200 mg desipramine (DMI). The experimental treatment was discontinued in 26 patients (10%): in 18 cases (5, 6 e 7 of the RBX, DMI and P group respectively) for inefficacy; in 3 cases for adverse events (2 of the RBX group due to deterioration of ventricular extrasystoles present before study start and hypertensive episodes respectively and 1 of the placebo group due to a cutaneous rash); in 5 cases (2, 1 and 2 in the RBX, DMI and P group respectively) for reasons unrelated to the experimental treatment.

Of the 80, 82 and 81 cases evaluable for efficacy in the RBX, DMI and P group (after exclusion of protocol violations, mainly related to associated treatments) 63%, 46% and 36% respectively showed a decrease >50% of the HAMD total score at the end of treatment; in 31%, 22% and 21% of these patients respectively the decrease was present within the 14th day of treatment. As to within-center results, the highest frequency of response was observed in the RBX group in all but 3 of the participating centers. After 2 and 4 weeks of treatment an average decrease of 23% and 34% of the HAMD was present in

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the P group; the corresponding figures were 34% and 49% in the DMI group and 39% e 57% in the RBX group. As to signs/symptoms, more frequent in the RBX group were headache, complained of by 33% of the patients (20% and 21% in the DMI e P group respectively), and urinary hesitancy/retention, present in 12% vs 4% vs 1% of the cases, RBX vs DMI vs P. More frequent in the DMI group were dry mouth (45% vs 26% vs 21%, DMI vs RBX vs P), sweating (28% vs 18% vs 22%), blurred vision (17% vs 4% in both RBX and P groups). Cardiovascular signs/symptoms were relatively rare, and appeared with slightly higher frequency in the DMI group: hypotension 13%, vs 6% in the RBX and 8% in the P group and tachycardia 19% vs 12% and 8% in the RBX and P group respectively.

3.0 RATIONALE

Phase II results obtained in controlled conditions in patients suffering from Major Depressive Disorders indicate that reboxetine is an effective antidepressant agent, with a favourable therapeutic index with respect to desipramine. Consistent information from further placebo-controlled studies is needed in order to properly document the activity and tolerability of the compound. In addition comparative evidence vs another tricyclic antidepressant is expected to allow a proper appraisal of the usefulness of the new molecule.

4.0 OBJECTIVES

To assess activity and tolerability of reboxetine in comparison with placebo and imipramine in patients suffering from Major Depressive Episodes.

5.0 DESIGN

5.1 Description

This phase III study will be carried out according to a double blind parallel group design, controlled vs imipramine and placebo, with random allocation of patients to one of the three treatments. The study will be organized on a multicentre, multinational basis.

5.2 Number of subjects proposed

Each center will recruit 24-42 patients, within a period of 12 months, for a total of 330 patients overall.

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5.3 Logistics

The centers participating in the study are listed in enclosure 1.

6.0 STUDY POPULATION

6.1 Source of subjects

- Adult patients selected from the population under in-patient care or attending out-patient or day-hospital clinics of the participating centers will be studied. These latter can be hospitalised for the study.

6.2 Inclusion criteria

- Patients affected by acute episodes of Major Depressive Episodes (DSM III R) (enclosure 2) not accompanied by psychotic features, with presence of episode for at least one month and not more than four.

- Patients of either sex, of any race, aged 18 to 65 years.

- A total score of 22 or above in the 21-HAMD.

- Patient's consent: informed written consent will be obtained - see 15.2 (proposed form: enclosure 3).

6.3 Exclusion criteria

- Dysthymia, Cyclothymia

- History of Major Depressive Episodes associated with Endocrine Disorders: hypo and hyper-thyroidism tested by TSH and T4 at screening and defined as at least 10% abnormal values of the laboratory norms; adrenal insufficiency, etc.

- Pregnancy (tested by pregnancy test at the end of the wash-out period).

- Refusal by female patients in potential child bearing age of efficient contraceptive use during the study period.

- Past history of any drug hypersensitivity.

- Participation in a clinical study with an investigational compound in the 4 weeks preceding the study.

- Evidence of Substance Use Disorder (DSM-III-R) within past 6 months or currently.

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-
- Chronic respiratory insufficiency in the physical examination and in X-ray.
 - Progressive illness or systemic disease of the digestive system, liver, or kidneys, or other conditions known to interfere with the absorption, distribution, metabolism and excretion of drugs.
 - History of seizures or brain injury; current evidence of clinically important hematopoietic or cardiovascular diseases. Current evidence of urinary retention, or glaucoma.
 - Symptoms of any other important clinical illness in the 4 weeks preceding the study.
 - Clinically relevant abnormal findings in the physical examination, laboratory tests and ECG at admission.
 - ECT in the previous 3 months.
 - MMS (mini mental State) < 22 (enclosure 4).
 - High risk of suicide.

6.4 Identification of subjects

Patients will be identified by their initials and by the number in the trial.

7.0 RANDOMIZATION PROCEDURES

A randomization list balanced within center will be prepared for patient allocation to one of the 3 possible treatments (reboxetine, imipramine or placebo). On this basis the experimental treatments will be prepared and labelled with the corresponding patient number.

Patient allocation to treatment will be done at the end of the pre-treatment period by the main Investigator on the basis of the patient's temporal entry into the study.

8.0 EXPERIMENTAL TREATMENTS

8.1 Test preparation

Indistinguishable capsules containing reboxetine 4 mg (2 tabl of 2 mg, batch no..) or 6 mg (3 tabl of 2 mg, batch no.....) or imipramine 50 mg (2 tabl of 25 mg, batch no.....) or 100 mg (4 tabl of 25 mg, batch no.....) or excipients only (placebo, batch no....) will be used. The experimental treatments will be administered according to fixed-flexible dose schedules as indicated under Study Conduct. Test preparations will consist of:

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	morning	evening
-reboxetine	1 cps 4 mg	1 cps 4 mg
-reboxetine DOSE 2 (last 3 weeks)	as above	1 cps 6 mg
-imipramine day 1-3	1 cps 50 mg	1 cps 50 mg
day 4-42	1 cps 50 mg	1 cps 100 mg
-imipramine DOSE 2 (last 3 weeks)	1 cps 100 mg	1 cps 100 mg
-placebo	1 cps	1 cps
-placebo DOSE 2 (last 3 weeks)	as above	as above

8.2 Labelling

The experimental treatment will be labelled by using the labels in enclosure 5. Double labels will be used.

8.3 Packaging

For each patient 6 cartons labelled with the patient number and the indication "week 1" to "week 6" will be prepared. Each carton will contain the medication necessary for 1 week plus 2 cps for possible losses, prepared according to the b.i.d. regimen with 1 cps for the "morning" and 1 cps for the "evening" dose. In addition for each patient 3 cartons labelled with the patient number and the indication "week 4-dose 2", "week 5-dose 2" and "week 6-dose 2" will be provided, for the possible dosage increase during the last 3 weeks of treatment (see Study Conduct).

8.4 Drug supplies storage

Drug supplies will be stored at room temperature. All drug supplies will be handled under the direct responsibility of the Investigator and held by the Hospital Pharmacy. The study Monitor will check drug storage conditions during site visits.

The Investigator will be also responsible for drug accountability and will keep a record of the test compounds received from the Sponsor as well as of the dispensed drug.

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8.5 Dispensing, use and disposition of test drugs during and at the end of the study

Medication will be dispensed to the patient on the occasion of each visit; the Investigator will detach the upper label from each of the weekly cartons he is dispensing to the patient and will attach them in the appropriate space in the Case Record Form. On the same occasion cartons of the possible previous supply will be returned by the patient.

Used cartons will be returned to the study Monitor during site visits.

All unused medication has to be returned to Farmitalia Carlo Erba at the end of the study.

9.0 STUDY CONDUCT

9.1 Pre-treatment period

Patients will be checked for eligibility according to the inclusion and exclusion criteria. A washout period of 4-7 days (14 days in case of MAOI administration) will then be undertaken, during which only chloral hydrate (0,5 - 1 g) as sleep inducer on p.r.n. basis will be allowed. Informed consent will be obtained from each patient.

Eligible patients will be then randomized to one of the three treatment groups and will undergo baseline assessments.

Information on patients screened for the study and found not to be eligible will be collected in the appropriate form (screening form, enclosure 6).

9.2 Treatment period

9.2.1 Dose/route of administration/treatment schedule

Treatments will be administered under close monitoring (hospital or day hospital for the first two weeks at least) to reduce suicidal risk to a minimum.

Patients will receive 1 capsule b.i.d. from day 1 to day 42. In case of inefficacy or unsatisfactory response (slight worsening or no change or minimal improvement at the CGI, see assessments), the dose will be increased to "dose 2" (see 8.0 Experimental Treatments) from day 22 to day 42, i.e. up to the end of treatment. In case of intolerance the dose will be reduced to the previously well tolerated lower dosage level.

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The treatments will be administered in the morning and in the evening, at least 2 hours before or after meals.

9.2.2 Duration of treatment

The experimental treatment will be administered for 6 weeks.

9.2.3 Indications for early termination of test therapy

Termination of test therapy prior to completion of the 6 weeks treatment period may be considered under the following circumstances:

- Patient's request
- Switch to mania
- Unacceptable toxicity: this is defined as the occurrence of serious (see Adverse Events) adverse events (see 12.0)
- Lack of efficacy: this will apply to patients who will show unacceptable deterioration after at least 2 weeks of treatment (worsening in CGI)

In case of treatment discontinuation the complete final battery of assessments will be carried out.

9.2.4 Dropouts/replacement of subjects

Patients who drop out of the study for any reason will not be substituted.

For those patients who have been selected for the study who drop out at any time, even if it is before entrance to the treatment period, documentation will be provided.

9.2.5 Concomitant therapy

No concomitant medications other than hypnotic on p.r.n. basis are allowed at entry into the study. Concomitant medication should be avoided throughout the study. In case the events arising during the course of the study nonpsychotropic medications which are considered necessary for the patient's welfare may be administered and will not be considered violation to the protocol. The drugs, dosage and frequency of administration will be recorded. Chloral hydrate (0.5-1g/night) as sleep inducer on p.r.n. basis at bed-time is allowed.

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9.2.6 Indications for opening the code

The Investigator will be given individual sealed envelopes containing the information on patient's treatment. These latter may be opened only in case of emergency necessitating treatment identification; the Investigator will immediately (within 24 hours) inform the study Monitor at FICE Subsidiaries and will report full description of reasons for opening the code in the CRF (Adverse Event Form).

The sealed individual codes will be returned to Farmitalia Carlo Erba at the end of the study.

9.3 Follow-up

A follow-up visit will be carried out for each patient one month after treatment discontinuation, in order to monitor possible withdrawal reactions and collect information on interval events.

Patients willing to continue receiving the experimental treatment after completion of the 6 weeks treatment period will be maintained under the same medication in blind conditions until completion of the last patient of the center. Monthly visits will be carried out for efficacy and safety assessment and drug dispensing. The medications will be prepared as described for the initial double-blind treatment period, but in monthly units.

Afterwards, patients will be followed-up in open conditions. Reboxetine tablets will be provided by Farmitalia Carlo Erba while, for those patients who were receiving imipramine, Tofranil will be prescribed.

9.4 Study timetable

Foreseen start date: September-October 90
Duration of accrual: 12 months
Foreseen end date (date of the last visit of the last patient, excluding follow up): November-December 91.

10.0 EFFICACY ASSESSMENTS

10.1 Variables to be measured for efficacy assessment

On days 0, 7, 14, 21, 28, 35, 42 :

- Hamilton Depression Rating Scale (21 items HAMD, enclosure 7); as above plus at screening for entry and monthly during the follow-up period.

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-
- Clinical Global Impression (Enclosure 8), as above plus monthly during the follow-up period.
 - Montgomery-Asberg Depression Rating Scale (Enclosure 9)
 - Patient Global Impression (Enclosure 10)-excluding day 0
 - Relational rating scales (Enclosure 11)

The latter is adopted in order to explore relational aspects of the Depressive Disorders ; Investigators are expected to propose 1-2 additional items of relevance for each patient in their opinion. Consistency of suggestions will be evaluated and on this basis an International Scale developed.

All psychiatric evaluations and ratings will be carried out by the same observer for a given patient, preferably in the same setting and at the same time of the day.

10.2 Efficacy definition

Decreases of at least 50 % in the total HAMD score vs day 0 will be considered index of response whereas total HAMD score of 10 or less will be considered index of remission.

10.3 Cognitive function evaluation

Cognitive function will be evaluated on the day 0, day 14, and at the end of the study according to the model tests described in Attachment C.

10.4 Criteria for subject evaluability

Every randomized patient will be included in the analysis.

11.0 SAFETY ASSESSMENT

11.1 Variables to be measured for safety assessment

- Standard medical history: at screening
- Standard clinical examination: full physical examination: at screening
- Blood pressure and pulse will be measured in the lying (after 5 minutes lying) and in the standing position (1 -2 minutes after standing up) in the morning: at screening and at each visit.

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- ECG: at screening, day 21, day 42 and every three months during follow-up.

- Chest X-ray: at screening

- Laboratory: TSH and T4 at screening; full blood count, sodium, potassium, chlorine, BUN, creatinine, glucose, bilirubin, calcium, phosphorus, SGOT, SGPT, gamma GT, alkaline phosphatase, LDH, total proteins, albumin, cholesterol, uric acid, triglycerides, globulins - α_1 , α_2 , β , gamma -, urinalysis: at screening, day 21, day 42 and every three months during follow-up.

- Adverse events: a check-list will be administered at each visit (Enclosure 12).

11.2 Criteria for subject evaluability

Every patient who has received at least one dose of the experimental treatment will be included in the safety evaluation.

12.0 ADVERSE EVENTS

Patients will be notified of possible adverse events they could experience and instructed to immediately report them to the Investigator.

Any newly observed sign or symptom, noticed by the Investigator or complained of by the patient, including clinically relevant lab abnormalities, will be recorded in the appropriate section of the CRF, regardless of presumed relationship to study medication.

For each event, the following information will be entered in the CRF: description, onset date, disappearance date, severity (1 = mild, awareness of sign or symptom, but easily tolerated; 2 = moderate, discomfort enough to cause interference with usual activity; 3 = severe, incapacitating with inability to work or do usual activity; 4 = unknown), drug cause-effect relationship (according to Karch and Lasagna modified criteria; see enclosure 13), outcome, dechallenge (what happened to the adverse event when the drug was stopped or the dose decreased?) rechallenge (what happened when the drug was restarted after the adverse event had disappeared?). The Investigator will also note if the double-blind code has been opened, the action taken regarding the test drug (none, discontinued, dosage reduced) and any treatment applied because of the adverse reactions.

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All serious* ("any experience that is (potentially) fatal or life-threatening, disabling, incapacitating, requires inpatient hospitalization, or causes a congenital anomaly or cancer or is due to overdose") and/or unexpected* ("any adverse experience that is not identified in nature, severity or frequency in the current investigator's brochure for the study") adverse events must be immediately (within 24 hours) reported by telephone to FICE Subsidiaries Monitors (see Section 17.0) and the Adverse Event Report Form (enclosure 14) must be filled in immediately. FICE will notify the Regulatory Authority in accordance with statutory requirements. The same applies to all patients who die, irrespective of whether the event was judged as related to treatment, during the course of the study or within 30 days of completion of treatment.

In case of death, if an autopsy is performed, a copy of the pathological report should be sent to the FICE subsidiary monitor.

13.0 EVALUATION SCHEDULE

Is reported in table 1.

14.0 STATISTICAL CONSIDERATIONS

14.1 Sample size

The main evaluation of treatment effectiveness will be based on the comparison with respect to placebo of the total score of the HAMD. The comparison will be performed on the difference between baseline and the last postbaseline score for each patient regardless of length of time in the study. Thus, this analysis, requiring at least one visit after baseline, takes into account differential dropout rates among treatment groups.

Either imipramine and reboxetine will be compared to placebo. The first comparison is set up in order to establish the sensitivity of the trial, while the second one will allow the evaluation of the new compound (reboxetine).

* Code of Federal Regulation, Vol 21 Part 312. Revised as of April 1, 1987, pg. 75.
* J.L.Bem et al.: Review of yellow cards (1986): report to the Committee on the Safety of Medicines.
Br.J. Clin. Pharmac. (1988), 26, 679-689.

Therefore the following hypothesis systems set up:

$$H_0: \delta_t \geq \delta_p \quad \text{i.e.} \quad \delta_t - \delta_p \geq 0$$

$$H_a: \delta_t < \delta_p \quad \delta_t - \delta_p < 0$$

where δ_t and δ_p represent respectively the true mean of the distribution of the difference from baseline of total score of the HAMD for reboxetine (or imipramine) and placebo.

In order to take into account the multiplicity of the comparisons, the criterion of Bonferroni is applied. Consequently the α level for the simultaneous inference is fixed at 0.025 for each comparison (overall α level = 0.05) (this is equivalent to the Dunnett procedure which would lead to an α level of 0.024 for each comparison).

From the phase II trial and from the literature (6) it seems reasonable to assume that treatment groups will show a variability (expressed as standard deviation) of 9 points. Considering of clinical relevance a difference between reboxetine, or imipramine, and placebo of at least 4 points, 80 patients per group are necessary in order to provide a power ≥ 0.80 if the alternative hypothesis is true, with the α level fixed at 0.025, for each of the two tests. Taking into account the possibility of dropouts before the first postbaseline visit and nonevaluable patients according to protocol criteria, 100 patients per group should be recruited.

14.2 Statistical analysis

The main analysis of treatment effectiveness will be carried out on the variable 'total score of HAMD' considering the difference between baseline and the last postbaseline score for each patient regardless of length of time in study. Both reboxetine and imipramine will be compared to placebo. Consistently with the method used for the sample size calculation a multiple t test procedure will be adopted to test the null hypothesis. Analysis of variance will produce the appropriate estimate of residual variability.

Evident unbalances among baseline values in the three groups will be taken into account by means of analysis of covariance.

As secondary aim reboxetine will be compared to imipramine in respect to HAMD total score considering the difference between baseline and the last postbaseline score for each patient. In this case a two tail test will be applied. Confidence interval of the difference between treatment mean decrements vs baseline will also be computed.

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In order to have a more complete picture of reboxetine effectiveness results obtained from the other administered scales (Montgomery-Asberg, CGI, PGI) as well as response/remission rates will be considered. Response/remission rate is defined as the proportion of randomized patients experiencing response/remission (see 10.2) at a fixed time.

All the efficacy variables will be analysed taking into account both the values obtained at the last postbaseline visit and values obtained at each week. Explorative comparisons among the three groups will be performed.

Time course of the score of the administered rating scales will be described for all the three groups. Time trend analysis will be performed on patients completing the six weeks treatment period. If judged to be informative, weekly analysis, including only those patients remaining in the study at a particular week, will be carried out.

Dropouts will be classified by reasons for study termination and proportions of patients dropped out compared among groups.

Frequencies of patients showing maximum decrease ≥ 20 mmHg in the standing systolic blood pressure will be compared among groups.

Adverse events will be presented by patient-by-patient listing and tabulated by treatment both on a patient basis and on an event basis. If clinically significant differences arise, they will be submitted to non parametric test of the differences among treatment groups.

Decriptive statistics (mean, median, etc.) for laboratory data will be provided as well as frequency of abnormal values, with respect to normal range, after treatment in each group.

15.0 ETHICAL ASPECTS

The study will be carried out according to the Helsinki Declaration (Venice revision, Enclosure 15)

15.1 Ethical Committee

This study will not be undertaken until approval is obtained from the Ethical Committee Institutional Review Board (IRB) of the participating centres. It is responsibility of the Investigator to submit the study protocol with its attachments to the Ethical Committee.

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The written approval of the Ethical Committee or IRB will report the name and profession of all its members and a copy of it will be sent to the Sponsor before the study begins.

The Investigator is committed, in compliance with local requirements, to inform the Ethical Committee of any emergent problems, serious adverse reactions or protocol amendments.

15.2 Informed consent

Before entering the study each patient will be receive an explanation of the nature, duration, and purpose of the study and the action of the compounds in such a manner that the patient is aware of the potential risks, inconveniences or adverse effects that may occur and can express his/her informed consent to participate. The consent form (enclosure 3) will be signed by the patient or by the next of kin and/or by the Investigator. In the latter case, the signature of a witness will testify that full information was given to the patient.

16.0 PROTOCOL AMENDMENTS

After the protocol has been signed, no changes will be made without the agreement of both the Investigator, the Steering Committee and the Sponsor. Any change will be recorded on a written agreement which will be signed and dated by both parties and attached to the original protocol. No protocol change will be implemented without Regulatory approval, where required.

17.0 STUDY MONITORING

The monitors of the study are listed in enclosure 16.

A pre-study visit will be made by the monitor to the Investigator in order to discuss problems, if any, and the obligations of both the Sponsor and the Investigator. During the trial monitoring visits will be paid to the site by the study monitor every four weeks. During the visits the monitor will assess the progress of the study, review the compliance with the study protocol, discuss any problem, check the CRFs for legibility, accuracy and completeness, validate CRFs content against source documents, assess the status of drug storage dispensing and retrieval.

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Operating procedures for training on assessment instruments, study monitoring and coordination are described in attachment A.

18.0 DRUG SUPPLY AND INVENTORY

Test preparation will be supplied by Farmitalia Carlo Erba in the form described in 8.1. Records will be kept by the Investigator as to the disposition of study drug for each patient. A disposition form accounting for all study supplies will be signed by the Investigator (enclosure 17).

19.0 ADMINISTRATIVE ASPECTS

19.1 Insurance policy (enclosure 18)

Farmitalia Carlo Erba Company declares to have a group insurance cover (policy NO. 4W8102 - Italia Assicurazioni) which provides indemnity to the Investigator, to the co-Investigators and to the subjects participating in the trial.

19.2 Curriculum vitae

The Investigator will provide the Sponsor with signed copies of his/her and his/her co- Investigators CVs.

19.3 Data collection in the Case Record Form

All study data will be recorded in the CRF supplied by the Sponsor (Attachment B). A black ink ball point pen should be used for entering the data to ensure the good quality of the reproduced CRFs copies.

Only the Principal Investigator and the duly authorized co-Investigators can make entries in the CRF.

In case of errors corrections must be made by crossing out the incorrect entry (that must remain legible) and entering the correction followed by the Investigator's initials and the date of the correction.

On the occasion of the monitoring visits the monitor will take away the original and one copy of each page, while the Investigator will retain a copy for his files, together with the drug disposition records, for ten years after the discontinuation of the investigation.

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19.4 Use and publication of the data obtained from the study

All unpublished documentation including the protocol, the CRF and the Investigator's Brochure, given to the Investigator is confidential. These documents cannot be disclosed to a third party without the written consent of FICE R&D. The submission of these documents to the Ethical Committee is expressly permitted.

The Investigator agrees that FICE R&D maintains the right to utilize the results of this study, in their original form and/or in a global report, for submission to the governmental and regulatory authorities of any country.

20.0 STUDY REPORT

20.1 Clinical Study Final Report

The final Medical Study Report will be written by the Product Leader and will be submitted to the Investigator for approval and signature.

20.2 Use and publication of Study Results

The Investigators, whilst free to use the data resulting from this study, are asked to discuss any paper with Farmitalia Carlo Erba prior to publication; to this purpose copy of manuscript/abstract as to be available for FICE R&D Approval Procedure 30 days prior to publication. The results of the study may be submitted for a common publication, agreed upon between the Investigator and FICE R&D.

21.0 END OF THE STUDY

The Investigator or FICE R&D could terminate this study at any time for well documented reasons. In this event the other party will be immediately notified.

22.0 STUDY COORDINATION

A Steering Committee in charge of the coordination of the study will be formed, as described in Attachment A.

565

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23.0 REFERENCES

1. Reboxetine Investigator Brochure, FICE, CNS Line, June 1988
2. /602i - Herrmann W.M. et al. (AFB - Berlin)
Safety and tolerance of reboxetine in healthy male volunteers - A single rising dose tolerance study.
June 15 1984.
3. /603i - Herrmann W.M. (AFB - Berlin)
Reboxetine - Quantitative pharmaco EEG and pharmacopsychological study.
January 1985.
4. /604i - Dubini A. et al.
Disposition and fate of ¹⁴C-reboxetine administered orally to healthy volunteers.
March 1985.
5. /701 - A. Dubini, T. Ban
Reboxetine: Open Dose Range Finding study in patients hospitalized for major depressive disorders
February 89
6. Stark P., Hardison D.
J. Clin. Psychiatry, 46:53-58, 1985

24.0 SIGNATURES

Signatures of the:

Investigator _____

Study Monitor _____

Product Leader John Payne

Line Medical Head Adriano Dubini

Biostatisticians Vicente Spera

566

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<u>TABLE 1</u>		<u>EVALUATION SCHEDULE</u>									
DAY	SCREEN	0	4	7	14	21	28	35	42		
RBX mg		8									
TREATMENT IMI mg		100-150				10					
PLACEBO						200					
DIAGNOSIS : DSM III R	■										
MEDICAL HISTORY	■										
PHYSICAL EXAMINATION	■										
MMS	■										
VITAL SIGNS	■	■		■	■	■	■	■	■	■	■
ECG	■					■					■
X-RAY	■										
LABORATORY	■					■					■
21-ITEM HAMD	■	■		■	■	■	■	■	■	■	■
CGI		■		■	■	■	■	■	■	■	■
MADRS		■		■	■	■	■	■	■	■	■
PATIENT GLOBAL IMPR.				■	■	■	■	■	■	■	■
RELATIONAL RATING SCALE		■		■	■	■	■	■	■	■	■
COGNITIVE EVALUATION		■			■						■
ADVERSE EVENTS		■		■	■	■	■	■	■	■	■

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LIST OF ENCLOSURES

- 1) LIST OF CENTERS
- 2) DSM-III-R CRITERIA
- 3) CONSENT FORM
- 4) MMS: MINI MENTAL STATE
- 5) EXPERIMENTAL TREATMENT LABELLING
- 6) SCREENING FORM
- 7) HAMD: HAMILTON DEPRESSION RATING SCALE
- 8) CGI: CLINICAL GLOBAL IMPRESSION
- 9) MADRS: MONTGOMERY ASBERG DEPRESSION RATING SCALE
- 10) PATIENT GLOBAL IMPRESSION
- 11) RDRS: RELATIONAL RATING SCALE
- 12) ADVERSE EVENTS: CHECK LIST
- 13) KARCH AND LASAGNA MODIFIED CRITERIA
- 14) ADVERSE EVENTS REPORT
- 15) DECLARATION OF HELSINKI
- 16) LIST OF MONITORS
- 17) DRUG ACCOUNTABILITY FORM
- 18) INSURANCE POLICY

ATTACHMENT A

PROTOCOL 20124/015: OPERATING PROCEDURES FOR TRAINING ON
ASSESSMENT INSTRUMENTS, STUDY MONITORING AND COORDINATION

ATTACHMENT B

CASE RECORD FORM

ATTACHMENT C

COGNITIVE FUNCTION EVALUATION

Appendix 1 : Manual for COGNITIVE EVALUATION
Appendix 2 : Manual for MEMORY ASSESSMENT

20124/015

Date: September 19, 1990

Page: 20 of 21

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Enclosure 1

LIST OF PARTICIPATING CENTERS

No.	Country	Principal Investigator (Institution, Address)	Number of patients
1.	Australia	Dr. Ramesh Gupta Phillip Health Centre Woden, Canberra	18
2.	France	Prof. Pellet Hopital Bellevue Boulevard Pasteur Service de Psychiatrie 42043 Saint Etienne Cedex	24
3.	France	Dr. Chabannes Clinique du Nivolet Service de Psychiatrie B.P. 126 73011 Chambéry Cedex	24
4.	France	Dr. Haxaire Cabinet Médical 15 bd Joffre A 54000 Nancy	24
5.	France	Prof. Leger Centre Hospitalier Spécialisé "Esquirol" 15 rue du Docteur-Marcland 87025 Limoges Cedex	24
6.	France	Dr. Cullerre Cabinet Médical 189 rue Colonel Jean Muller 56000 Lorient	24
7.	Germany	Dr. E.U. Vorbach Psychiatrische Klinik Elisabethenstift Landgraf-Georg Str. 100 6100 Darmstadt	24

20124/015

Date: September 19, 1990

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8. Italy	Prof. E. Aguglia Department of Psychiatry University of Trieste via s. Cilino 16 34126 Trieste phone:040/671077	24
9. Italy	Prof. E.Smeraldi Ospedale San Raffaele Villa Turro via Prinetti 29 20127 Milano phone: 02/28043229	24
10. Sweden	Dr. B. Wistedt Danderyd's Hospital Stockholm	24
11. United Kingdom	Prof. R.G.Priest Academic Department of Psychiatry St. Marys Hospital Pread Street London W2 1NY phone: 0717251648	42
12. Canada	Prof. M. Ohayon Center of Research Hopital Loui Lafontaine 7401 Rue Hochelaga Montreal, Que H1N 3M5 phone: 514/2514015	36
13. Australia	Prof. G.D.Burrows Department of Psychiatry University of Melbourne Austin Hospital, Heidelberg, Vic. 3084 phone: 450-5111	18
14. "	Prof. J. Tiller Royal Hospital Melbourne	12
15. "	Dr. T. George Prince Charles Hospital Brisbane	12

Enclosure 2

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2012401

Centre No.

Pat. Initials 9550082

Visit/cycle SCREE

Date
D M Y

DSM-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Note: all A, B, C and D must be marked as "present"

Mark "X" if present

A. At least five of the following symptoms have been present during the same two-week period and represent a change from previous functioning; at least one of the symptoms is either 1) depressed mood or 2) loss of interest or pleasure.

- 1) depressed mood most of the day, nearly every day, as indicated by subjective account or observation by others
- 2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated either by subjective account or observation by others of apathy most of the time)
- 3) significant weight loss or weight gain when not dieting (e.g. more than 5% of body weight in a month), or decrease or increase in appetite nearly every day
- 4) insomnia or hypersomnia nearly every day
- 5) psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
- 6) fatigue or loss of energy nearly every day
- 7) feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
- 8) diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
- 9) recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

"A" present.....

- B. 1) It cannot be established that an organic factor initiated and maintained the disturbance
2) The disturbance is not a normal reaction to the death of a loved one

"B" present.....

C. At no time during the disturbance have there been delusions or hallucinations for as long as two weeks in the absence of prominent mood symptoms (i.e., before the mood symptoms developed or after they have remitted)

"C" present.....

D. Not superimposed on Schizophrenia, Schizophreniform, Disorder, Delusional Disorder, or Psychotic Disorder NOS.

"D" present.....

571

Investigator's signature _____

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

ENCLOSURE No. 3

9550082

REBOXETINE PROTOCOL 20124/015

Multicenter, multinational double blind study of the activity and tolerability of reboxetine vs imipramine and placebo in patients suffering from Major Depressive Disorders.

CONSENT FORM

Principal Investigator:

EXPLANATION

Purpose of the study

Reboxetine, a new potential antidepressant agent, has effects in animals which suggest that it may exert therapeutic efficacy of faster onset, in comparison with established antidepressant drugs, in patients suffering from depressive disorders. The trial is proposed in order to learn about the antidepressant effectiveness of the compound and its tolerability.

Plan of the study

After an initial drug free wash out period of at least one week, patients will receive either reboxetine or imipramine, an antidepressant of established efficacy, available on the market in most countries or a harmless inactive treatment (placebo). Neither patients nor doctors will know which treatment will be administered in individual cases until after the study is completed. The identity of the treatments can anyhow be determined immediately if any medical problem will develop and it will become important to learn which of the two possible treatments is being given.

Treatment will be administered for six weeks. It will be discontinued in case of deterioration of psychiatric symptomatology or in case of significant side-effects. In addition patients participating in the study may withdraw their consent at any time without prejudice to their continued medical treatment.

During treatment, physical and psychiatric examinations will be done on frequent occasions, in order to determine

1

Cont'd Encl. 3

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possible side-effects and benefits of treatments. Blood tests, urinalysis, ECG will be undertaken be-weekly. Blood pressure and pulse will be taken every week, on the occasion of each visit.

Possible discomforts and risks

Antidepressant drugs can cause dry mouth, blurred vision, dizziness, mild difficulty in voiding urine, postural hypotension and electrocardiographic changes.

Reboxetine has been so far administered for 28 days to about 180 patients and was well tolerated up to the dose of 5 mg twice daily. In the dose range of 3-5 mg twice daily clinically relevant improvement of depressive condition was present in the majority of patients; symptoms complained off by patients were mainly mild and transient and included most frequently headache, sweating, lassitude, nasal congestion, constipation and urinary hesitancy. At higher doses orthostatic hypotension, tachycardia, dizziness, blurred vision and nausea were reported.

Patients participating in the study will be carefully monitored to detect early signs of such side-effects.

Possible benefits

Other drugs are available for treatment of depressive disorders but none has been of proven value in all cases. This study will allow the evaluation of the antidepressant activity of reboxetine in comparison with placebo (associated to a response rate of 30-40% in acute depressive episodes) and imipramine, a compound of established efficacy. The evaluation of patient response under placebo could be useful in deciding the most appropriate treatment approach in individual cases.

Alternative treatment

Patients would receive alternative pharmacological therapy with an antidepressant drug chosen on the basis of response during previous episodes, if any. Risks and benefits of receiving treatment with any of the available antidepressant drugs can be explained by

Confidentiality

Participation in the study will be kept confidential to the extent permitted by law.

Cont'd Encl. 3

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Problems and questions

Should any problem or question arise with regard to the study, patients can contact the Principal Investigator:

.....
or the other staff members also involved in the study:
.....
.....
.....

In addition any problem or question can be discussed with a member of the Institutional Review Board (.....), the Committee which has evaluated the potential risks and possible benefits of the study.

Payments and policy regarding research-related injuries.

Patients will not be paid for the participation in the study. The Clinical Center will provide short-term medical care for any physical injury resulting from participation in the study. No long-term medical care or financial compensation for such injuries will be provided except as it may be through whatever remedies are normally available under law. Insurance coverage is granted through the Sponsor Company.

PATIENTS CONSENT

I have read the explanation about this study and I have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Patient Signature

date

I have explained all the above indicated aspects of the study to the patient, who expressed his/her consent to the participation.

Investigator Signature

date

Witness Signature

date

Enclosure 4

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**
9550082

Protocol No. 2|0|1|2|4|0|1

Centre No. [][][][][]

Pat. Initials [][][]

Visit/cycle |S|C|R|E|E

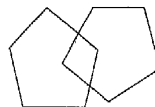
Date [][][][][][]
D M Y

THE MINI-MENTAL STATE EXAMINATION

	Score	Points
Orientation		
1. What is the		
Year?	-	1
Season?	-	1
Date?	-	1
Day?	-	1
Month?	-	1
2. Where are we?		
State?	-	1
County?	-	1
Town or city?	-	1
Hospital?	-	1
Floor?	-	1
Registration		
3. Name three objects, taking one second to say each. Then ask the patient all three after you have said them. Give one point for each correct answer. Repeat the answers until the patient learns all three.	-	3
Attention and calculation		
4. Serial sevens. Give one point for each correct answer. Stop after five answers. ALTERNATE: Spell WORLD backwards.	-	5
Recall		
5. Ask for names of three objects learned in Question 3. Give one point for each correct answer.	-	3
Language		
6. Point to a pencil and a watch. Have the patient name them as you point.	-	2
7. Have the patient repeat "No ifs, ands, or buts."	-	1
8. Have the patient follow a three-stage command: "Take the paper in your right hand. Fold the paper in half. Put the paper on the floor".	-	3
9. Have the patient read and obey the following: "CLOSE YOUR EYES". (Write it in large letters.)	-	1
10. Have the patient write a sentence of his or her own choice. (The sentence should contain a subject and an object and should make sense. Ignore spelling errors when scoring.)	-	1
11. Enlarge the design printed below to 1-5 cm per side and have the patient copy it. (Give one point if all sides and angles are preserved and if the intersecting sides form a quadrangle.)	-	1

_____ = Total 30

575



Investigator's signature _____

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Enclosure 5

9550082

REBOXETINE PROTOCOL 20124/015
EXPERIMENTAL TREATMENT LABELLING

TREATMENT PHASE:

reboxetine protocol 20124/015
patient No.....
week 1 - 6
batch No.....
expiry.....
drug for investigational use

DOSE 2 TREATMEN PHASE:

reboxetine protocol 20124/015
patient No.....
week 4 - 6
batch No.....
expiry.....
drug for investigational use

Enclosure 6



Patient initials

Hospital File/Out Patient Reg. N°

Phase III

**Multicenter, multinational
double-blind study
of the activity and
tolerability of reboxetine
vs imipramine and
placebo in patients
suffering from major
depressive episodes**

PROTOCOL 20124/015

SCREENING FORM

Investigator's signature _____

577

ERBAMONT GROUP

Cont. 'd enclosure 6

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124011

Centre No. [][][][]

Pat. Initials **9550082**

Visit/cycle **S|C|R|E|E|**

Investigator's name _____

Monitor's name _____

Date [][][] [][][] [][][]
D M Y

PATIENT IDENTIFICATION

Hospital File/Out Pat. Register N° [][][][][][][][][]

Initials [][][]

Sex M F

Age (years) [][][]

Weight (kg) [][][][]

Height (cm) [][][][]

Birth date [][][][][][][][][][]
D M Y

Ethnic group: Caucasian Black Asian Other , specify _____

Out-patient

In patient , hospitalized on [][][][][][][][][][]
D M Y

DIAGNOSIS

- DSM-III-R AXIS I _____

HISTORY OF THE MENTAL DISORDER:

Unknown if known:

- Age of onset of disease

years [][][]

- Number of previous episodes

[][][]

- Approximate duration of last episode

weeks [][][] months [][][] years [][][]

PRESENT EPISODE

- Approximate duration at the time of admission to the study days [][][][] weeks [][][][] months [][][][] years [][][]

THE PRESENT EPISODE IS BEST CHARACTERIZED AS:

- Exacerbation of chronic condition 1

- Recurrence of similar previous conditions 2

- Significantly different from any previous conditions 3

- First occurrence, no previous psychiatric diagnosis 4

ONSET OF PRESENT EPISODE WAS:

- Acute (<2 weeks) 1

- Subacute (≥ 2 weeks) 2

- Insidious (≥ 3 months) 3

PRECIPITATING EXTERNAL STRESS WAS:

- Absent 1

- Probably present 2

- Definitely present 3

578

1-screen

Investigator's signature _____

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FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETIN**

Cont. id enclosure
Protocol No. 2012401

Centre No. [][][][][][]

Pat. Initials **9550082**

Visit/cycle [S][C][R][E][I]

Date [][][][][][][]
D M Y

THE MINI-MENTAL STATE EXAMINATION

	Score	Points
Orientation		
1. What is the Year?	-	1
Season?	-	1
Date?	-	1
Day?	-	1
Month?	-	1
2. Where are we? State?	-	1
County?	-	1
Town or city?	-	1
Hospital?	-	1
Floor?	-	1
Registration		
3. Name three objects, taking one second to say each. Then ask the patient all three after you have said them. Give one point for each correct answer. Repeat the answers until the patient learns all three.	-	3
Attention and calculation		
4. Serial sevens. Give one point for each correct answer. Stop after five answers. ALTERNATE: Spell WORLD backwards.	-	5
Recall		
5. Ask for names of three objects learned in Question 3. Give one point for each correct answer.	-	3
Language		
6. Point to a pencil and a watch. Have the patient name them as you point.	-	2
7. Have the patient repeat "No ifs, ands, or buts."	-	1
8. Have the patient follow a three-stage command: "Take the paper in your right hand. Fold the paper in half. Put the paper on the floor".	-	3
9. Have the patient read and obey the following: "CLOSE YOUR EYES". (Write it in large letters.)	-	1
10. Have the patient write a sentence of his or her own choice. (The sentence should contain a subject and an object and should make sense. Ignore spelling errors when scoring.)	-	1
11. Enlarge the design printed below to 1-5 cm per side and have the patient copy it. (Give one point if all sides and angles are preserved and if the intersecting sides form a quadrangle.)	-	1

_____ = Total 30

580



3-scre

Investigator's signature _____

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FARMITALIA CARLO ERBA
Erasmont Group

Compound **REBOXYTINE**

Cont'd enclosure 6

Protocol No. 20124011

Centre No. [][][][]

Pat. Initials **9550082**

Visit/cycle **S|C|R|E|E|N**

Date [][][]
D M Y

HAMD: HAMILTON DEPRESSION RATING SCALE

1. Depressed mood (*Sadness, hopeless, helpless, worthless*)

- Absent These feeling states indicated only on questioning
 These feeling states spontaneously reported verbally
 Communicates feeling states non-verbally - i.e., through facial expression, posture, voice, and tendency to weep
 Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication

2. Feelings of guilt

- Absent Self reproach, feels he has let people down
 Ideas of guilt or rumination over past errors or sinful deeds
 Present illness is a punishment. Delusions of guilt
 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

- Absent Feels life is not worth living
 Wishes he were dead or any thoughts of possible death to self
 Suicide ideas or gesture
 Attempts at suicide (*any serious attempt rates 4*)

4. Insomnia early

- No difficulty falling asleep Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
 Complains of nightly difficulty falling asleep

5. Insomnia middle

- No difficulty Patient complains of being restless and disturbed during the night
 Waking during the night - any getting out of bed rates 2 (*except for purposes of voiding*)

6. Insomnia late

- No difficulty Waking in early hours of the morning but goes back to sleep
 Unable to fall asleep again if he gets out of bed

7. Work and activities

- No difficulty
 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
 Loss of interest in activity; hobbies or work - either directly reported by patient, or indirect in listlessness, indecision and vacillation (*feels he has to push self to work or activities*)
 Decrease in actual time spent in activities or decrease in productivity. In hospital, rate 3 if patient does not spend at least three hours a day in activities (*hospital job or hobbies*) exclusive of ward chores
 Stopped working because of present illness. In hospital, rate 4 if patient engages in no activities except ward chores, or if patient fails to perform ward chores unassisted

4-scre

581 Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Cont. ' d enclosure 6

Protocol No. 2|0|1|2|4|0|1|5

Centre No. [][][][][]

Func. initials [][][] **9550082**

Visit/cycle **S|C|R|E|E|N**

Date [][][][][][]
D M Y

8. Retardation (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

- 0 Normal speech and thought
- 1 Slight retardation at interview
- 2 Obvious retardation at interview
- 3 Interview difficult
- 4 Complete stupor

9. Agitation

- 0 None
- 1 Fidgetiness
- 2 Playing with hands, hair, etc.
- 3 Moving about, can't sit still
- 4 Hand wringing, nail biting, hair-pulling, biting of lips

10. Anxiety psychic

- 0 No difficulty
- 1 Subjective tension and irritability
- 2 Worrying about minor matters
- 3 Apprehensive attitude apparent in face or speech
- 4 Fears expressed without questioning

11. Anxiety somatic

Physiological concomitants of anxiety, such as: Gastro-intestinal (*dry mouth, wind, indigestion, diarrhea, cramps, belching*); Cardio-vascular (*palpitations, headaches*); Respiratory (*hyperventilation, sighing*); Urinary frequency; Sweating

- 0 Absent
- 1 Mild
- 2 Moderate
- 3 Severe
- 4 Incapacitating

12. Somatic symptoms gastrointestinal

- 0 None
- 1 Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen
- 2 Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. Somatic symptoms general

- 0 None
- 1 Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability
- 2 Any clear-cut symptoms rates 2

14. Genital symptoms (Such as: Loss of libido; Menstrual disturbances)

- 0 Absent
- 1 Mild
- 2 Severe

15. Hypochondriasis

- 0 Not present
- 1 Self-absorption (bodily)
- 2 Preoccupation with health
- 3 Frequent complaints, requests for help, etc.
- 4 Hypochondriacal delusions

5-screa

582

Investigator's signature _____

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FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Cont.'d enclosure 6

Protocol No. 20124011

Centre No. [][][][][]

Pat. Initials **9550082**

Visit/cycle **S | C | R | E | E | N**

Date [][][] [][][] [][][]
D M Y

16. Loss of weight Rate either A or B

A. When Rating By History:

- 0: No weight loss
- 1: Probable weight loss associated with present illness
- 2: Definite (according to patient) weight loss
- 3: Not assessed

B. On Weekly Ratings By Ward Psychiatrist, When Actual Weight Changes Are Measured:

- 0: Less than 1 lb. weight loss in week
- 1: Greater than 1 lb. weight loss in week
- 2: Greater than 2 lb. weight loss in week
- 3: Not assessed

17. Insight

- 0: Acknowledges being depressed and ill
- 1: Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
- 2: Denies being ill at all

18. Diurnal variation

A. Note Whether Symptoms Are Worse In Morning Or Evening. If NO Diurnal Variation, Mark "none":

- 0: No variation
- 1: Worse in A.M.
- 2: Worse in P.M.

B. When Present, Mark The Severity Of The Variation. Mark "None" If NO Variation:

- 0: None
- 1: Mild
- 2: Severe

19. Depersonalization and derealization (Such as: Feelings of unreality, Nihilistic ideas)

- 0: Absent
- 1: Mild
- 2: Moderate
- 3: Severe
- 4: Incapacitating

20. Paranoid symptoms

- 0: None
- 1: Suspicious
- 2: Ideas of reference
- 3: Delusions of reference and persecution

21. Obsessional and compulsive symptoms

- 0: Absent
- 1: Mild
- 2: Severe

Total score [][]

583

6-scree

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Centre No. [][][][][]

Pat. Initials **9550082**

Cont. 'd enclosure 6
Protocol No. 20124011

Visit/cycle **S|C|R|E|N**

Date [][][][][][]
D M Y

ADMISSION EXAMINATION

CHEST X-RAY taken on [][][][][][] normal abnormal
D M Y

If abnormal, detail _____

VITAL SIGNS

- Body temperature (°C) [][][]

- Respiratory rate (breaths/min) [][][]

- 5 min lying arterial blood pressure (mmHg) systolic [][][] diastolic [][][]

- 5 min lying heart rate (beats/min) [][][]

- 2 min standing arterial blood pressure (mmHg) systolic [][][] diastolic [][][]

- 2 min standing heart rate (beats/min) [][][]

MEDICAL HISTORY

- Important previous diseases _____

584

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Investigator's signature _____

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Cont.'d enclosure 6

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|

Centre No. [][][][][]

Pat. Initials **9550082**

Visit/cycle **S|C|R|E|E|i**

Date [][][][][][][]
D M Y

ECG

HEART RATE [][][][]

- Normal
- Abnormal

if abnormal check one or more boxes as appropriate:

- 1 Sinus bradycardia (<60)
- 2 Sinus tachycardia (>100)
- 3 Sick Sinus Syndrome

- Atrial ectopic beats:
 - Occasional
 - Frequent (>6/mm)
 - Couplets
 - Supraventricular Tachycardia

- Ventricular ectopic beats:
 - Occasional
 - Frequent (>6/mm)
 - Polymorphic
 - Couplets
 - Ventricular Tachycardia

- Atrial fibrillation/flutter
- A-V Block 1st degree
- 2nd degree - Mobitz 1
- Mobitz 2
- Complete

- Left ventricular hypertrophy
- Right ventricular hypertrophy
- Myocardial ischemia
- Previous Myocardial infarction
- Acute Myocardial infarction
- Right bundle branch block
- Left bundle branch block
- Left anterior hemiblock
- Left posterior hemiblock
- Bifascicular Block (specify)
- Trifascicular Block (specify)
- Other
- (specify) _____

585

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FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Cont. 'd enclosure 6

Protocol No. 20124011

Centre No. [][][][][]

Pat. Initials **9550082**
[][][]

Visit/cycle S | C | R | E | E | R

Date [][][][][][][]
D M Y

CONT' ECG

Please, add here the ORIGINAL TRACING AND MEDICAL REPORT

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586

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Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Cont. 'd enclosure 6
Protocol No. 2012401

Centre No. [][][][][]

Pat. Initials [][][] **9550082**

Visit/cycle **S | C | R | E | E |**

Date [][][] [][][] [][][]
D M Y

LABORATORY TESTS

Tests	Value	Clinically Significant abnormality**	Tests	Value*	Clinically Significant abnormality
BLOOD TESTS			BUN		<input type="checkbox"/>
HB		<input type="checkbox"/>	Creatinine		<input type="checkbox"/>
HCT		<input type="checkbox"/>	Uric acid		<input type="checkbox"/>
RBC		<input type="checkbox"/>	Total bilirubin		<input type="checkbox"/>
WBC		<input type="checkbox"/>	Direct bilirubin		<input type="checkbox"/>
Neutrophils		<input type="checkbox"/>	Total protein		<input type="checkbox"/>
Lymphocytes		<input type="checkbox"/>	Blood albumin		<input type="checkbox"/>
Eosinophils		<input type="checkbox"/>	Cholesterol*		<input type="checkbox"/>
Monocytes		<input type="checkbox"/>	Triglycerides*		<input type="checkbox"/>
Basophils		<input type="checkbox"/>	Globulins: α 1		<input type="checkbox"/>
Platelets		<input type="checkbox"/>	α 2		<input type="checkbox"/>
Na ⁺		<input type="checkbox"/>	β		<input type="checkbox"/>
K ⁺		<input type="checkbox"/>	γ		<input type="checkbox"/>
CL ⁻		<input type="checkbox"/>	TSH		<input type="checkbox"/>
Ca ⁺⁺		<input type="checkbox"/>			<input type="checkbox"/>
PO ₄		<input type="checkbox"/>	T ₄		<input type="checkbox"/>
SGOT		<input type="checkbox"/>	URINALYSIS		
SGPT		<input type="checkbox"/>	Specific gravity		<input type="checkbox"/>
γ-GT		<input type="checkbox"/>	Albumin		<input type="checkbox"/>
LDH		<input type="checkbox"/>	Sugar		<input type="checkbox"/>
Alkaline phosphatase		<input type="checkbox"/>	RBC		<input type="checkbox"/>
Blood sugar*		<input type="checkbox"/>	WBC		<input type="checkbox"/>

* Fasting blood sample is required
** Cross in case of clinically significant abnormality

587

Observation: _____

10-screed

Investigator's signature _____

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETIN**

Centre No.

Pat. Initials **9550082**

Cont. 'd enclosure 6
Protocol No. **20124011**

Visit/cycle **S|C|R|E|E**

Date

PREVIOUS TREATMENTS

NAME*	EFFICACY (Very poor, Poor, Fair, Good, Very good)	SIDE EFFECTS (if any)
	VP P F G VG	<input type="text"/>
	VP P F G VG	<input type="text"/>
	VP P F G VG	<input type="text"/>
	VP P F G VG	<input type="text"/>
	VP P F G VG	<input type="text"/>

Last treatment taken: name* Last day of treatment

Drug free. Wash-Out Period: from to

CONCOMITANT DRUGS (during the drug free, wash-out period)

NAME*	Daily Dose (mg)	Started on (date)			Discontinued on (date)			Reason for the administration
		D	M	Y	D	M	Y	

* Whenever possible use non-proprietary name instead of trade name

Observations:

588

11-screer Investigator's signature

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MITALIA CARLO ERBA
Erbarmont Group

Compound **REBOXYTINE**

Centre No.

Pat. Initials **9550082**

Cont.'d enclosure 6
Protocol No. **2|0|1|2|4|0|1|5**

Visit/cycle **S|C|R|E|E|E**

Date

PRE-STUDY CHECKLIST

IN THE PATIENT:

ARE THE FOLLOWING CONDITIONS PRESENT?	YES	NO
- Aged between 18 and 65 years inclusive?	<input type="checkbox"/>	<input type="checkbox"/>
- Affected by acute episodes of Major Depressive Episodes (DSM-III-R), not accompanied by psychotic features with presence of episode for at least one month and not for more than four?	<input type="checkbox"/>	<input type="checkbox"/>
- With a total score of 22 or above in the 21-HAMD?	<input type="checkbox"/>	<input type="checkbox"/>
- Able and willing (he/she or the next of kin) to give Informed Consent?	<input type="checkbox"/>	<input type="checkbox"/>
ARE THE FOLLOWING CONDITIONS ABSENT?		
- Dysthymia?	<input type="checkbox"/>	<input type="checkbox"/>
- History of Major Depressive Episodes, associated to Endocrine Disorders?	<input type="checkbox"/>	<input type="checkbox"/>
- Pregnancy? (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>
- Refusal of contraceptive use during the study period? (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>
- Clinically significant hematopoietic abnormality?	<input type="checkbox"/>	<input type="checkbox"/>
- Clinically significant lab values abnormality?	<input type="checkbox"/>	<input type="checkbox"/>
- Current evidence of urinary retention?	<input type="checkbox"/>	<input type="checkbox"/>
- Current evidence of glaucoma?	<input type="checkbox"/>	<input type="checkbox"/>
- Clinically significant physical abnormality?	<input type="checkbox"/>	<input type="checkbox"/>

If NO, please cross and detail:

- Hepatic function : _____

- Renal function : _____

- Gastrointestinal function : _____

- Cardiovascular function : _____

12-screen

589

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Cont.' d enclosure 6
Protocol No. 20124015

Centre No. [][][][][]

Pat. Initials [][][] **9550082**

Visit/cycle [S][C][R][E][N]

Date [][][][][][][]
D M Y

(CONT'D)

ARE THE FOLLOWING CONDITIONS ABSENT?	YES	NO
- Participation in a clinical trial with an investigational compound in the 4 weeks preceding the study?	<input type="checkbox"/>	<input type="checkbox"/>
- Evidence of substance use disorder within past 6 months or currently?	<input type="checkbox"/>	<input type="checkbox"/>
- Chronic respiratory insufficiency?	<input type="checkbox"/>	<input type="checkbox"/>
- History of drug hypersensitivity?	<input type="checkbox"/>	<input type="checkbox"/>
- Any history of seizures or brain injury?	<input type="checkbox"/>	<input type="checkbox"/>
- Any other important clinical illness in the 4 weeks preceding the study?	<input type="checkbox"/>	<input type="checkbox"/>
- ECT in the previous 3 months?	<input type="checkbox"/>	<input type="checkbox"/>
- MMS < 22?	<input type="checkbox"/>	<input type="checkbox"/>
- High risk of suicide?	<input type="checkbox"/>	<input type="checkbox"/>

If the answer to any of the above questions is NO the patient is unsuitable for entry into the study and should not proceed further.

CONCLUSION

I, dr. _____ confirm that the available informations on the patient agree with exclusion and inclusion criteria and that the patient is suitable to be included in this study and will receive the following patient number [][][][] .

590

13-scre

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Enclosure 7
Protocol No. [2|0|1|2|4|0|1|5]

Centre No. [] [] [] [] [] [] Patient No. [] [] [] [] [] [] Initials **9550082** Visit/cycle [D|A|Y|] [] [] [] [] [] []
Date [] [] [] [] [] [] [] [] [] []
D M Y

HAMD: HAMILTON DEPRESSION RATING SCALE

1. Depressed mood (*Sadness, hopeless, helpless, worthless*)

- 0 Absent 1 These feeling states indicated only on questioning
- 2 These feeling states spontaneously reported verbally
- 3 Communicates feeling states non-verbally - i.e., through facial expression, posture, voice, and tendency to weep
- 4 Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication

2. Feelings of guilt

- 0 Absent 1 Self reproach, feels he has let people down
- 2 Ideas of guilt or rumination over past errors or sinful deeds
- 3 Present illness is a punishment. Delusions of guilt
- 4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide

- 0 Absent 1 Feels life is not worth living
- 2 Wishes he were dead or any thoughts of possible death to self
- 3 Suicide ideas or gesture
- 4 Attempts at suicide (*any serious attempt rates 4*)

4. Insomnia early

- 0 No difficulty falling asleep 1 Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
- 2 Complains of nightly difficulty falling asleep

5. Insomnia middle

- 0 No difficulty 1 Patient complains of being restless and disturbed during the night
- 2 Waking during the night - any getting out of bed rates 2 (*except for purposes of voiding*)

6. Insomnia late

- 0 No difficulty 1 Waking in early hours of the morning but goes back to sleep
- 2 Unable to fall asleep again if he gets out of bed

7. Work and activities

- 0 No difficulty
- 1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
- 2 Loss of interest in activity; hobbies or work - either directly reported by patient, or indirect in listlessness, indecision and vacillation (*feels he has to push self to work or activities*)
- 3 Decrease in actual time spent in activities or decrease in productivity. In hospital, rate 3 if patient does not spend at least three hours a day in activities (*hospital job or hobbies*) exclusive of ward chores
- 4 Stopped working because of present illness. In hospital, rate 4 if patient engages in no activities except ward chores, or if patient fails to perform ward chores unassisted

591 Investigator's signature _____

Enclosure 8

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124015

Centre No. [][][][][]

Patient No. [][][][]

9550082
Initials [][][][]

Visit/cycle DAY [][][]

Date [][][][][][]
D M Y

CLINICAL GLOBAL IMPRESSION (CGI)

A. SEVERITY OF ILLNESS

Considering your clinical experience with this particular population, how mentally ill is the patient at this time?

- 1 Normal, not at all ill
- 2 Borderline mentally ill
- 3 Mildly ill
- 4 Moderately ill
- 5 Markedly ill
- 7 Severely ill
- 8 Among the most extremely ill patients

B. GLOBAL IMPROVEMENT (rate total improvement whether or not, in your judgement, it is due entirely to drug treatment)

Compared to this condition at admission to the study, how much has he changed?

- 1 Very much improved
- 2 Much improved
- 3 Minimally improved
- 4 No change
- 5 Minimally worse
- 6 Much worse
- 7 Very much worse

C. EFFICACY INDEX (rate this item on the basis of drug effect only)

Activity	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED Vast improvement, complete or nearly complete remission of all symptoms	1	2	3	4
MODERATE Decided improvement, partial remission of symptoms	5	6	7	8
MINIMAL Slight improvement which does not alter status of care of patient	9	10	11	12
UNCHANGED OR WORSE	13	14	15	16

594

Investigator's signature _____

Enclosure 9

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|5

Centre No. [] [] [] []

Patient No. [] [] [] []

Initials 9550082

Visit/cycle D|A|Y [] [] []

Date [] [] [] [] [] []
D M Y

MADRS: MONTGOMERY ASBERG DEPRESSION RATING SCALE

1. Reported sadness

- Representing subjectively experienced mood, regardless of whether it is reflected in appearance or not. Includes depressed mood, low spirits, despondency, and the feeling of being beyond help and without hope.
- Rate according to intensity, duration and the extent to which the mood is influenced by events.
- Elated mood is scored zero on this item.

Occasional sadness may occur in the circumstances [0]; Predominant feelings of sadness, but brighter moments occur [1]; Pervasive feelings of sadness or gloominess, the mood is hardly influenced by external circumstances [2]; Continuous experience of misery or extreme despondency [3].

2. Inner tension

- Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to panic, dread and anguish.
- Rate according to intensity, frequency, duration and the extent of reassurance called for.
- Distinguish from sadness, worrying and muscular tension.

Placid, only fleeting inner tension [0]; Occasional feelings of edginess and ill-defined discomfort [1]; Continuous feelings of inner tension, or intermittent panic which the patient can only master with some difficulty [2]; Unrelenting dread or anguish, overwhelming panic [3].

3. Apparent sadness

- Representing despondency, gloom and despair (more than just ordinary transient low spirits) reflected in speech, facial expression, and posture, rate by depth and inability to brighten up.

No sadness [0]; Looks dispirited but brightens up occasionally [1]; Appears sad and unhappy all of the time [2]; Extreme and continuous gloom and despondency [3].

4. Suicidal thoughts

- Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.
- Suicidal attempts should not in themselves influence the rating.

Enjoys life or takes it as it comes [0]; Weary of life, only fleeting suicidal thoughts [1]; Much better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention [2]; Explicit plans for suicide when there is an opportunity, active preparation for suicide [3].

5. Inertia

- Representing a difficulty getting started or slowness initiating and performing everyday activities
- Distinguish from indecision and fatigability.

No difficulty in getting started, No sluggishness [0]; Difficulties in starting new activities [1]; Difficulties in starting very simple routine activities, which are carried out only with effort [2]; Complete inertia, unable to start any activity without help [3].

6. Inability to feel

- Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is produced.
- Distinguish from inertia

Normal interest in the surroundings and in other people [0]; Reduced ability to enjoy usual interests. Reduced ability to feel anger [1]; loss of interest in the surroundings. Loss of feelings for friends and acquaintances [2]; The experience of being emotionally paralyzed, inability to feel anger or grief, and a complete or even painful failure to feel for close relatives and friends [3].

595

Investigator's signature _____

Cont. 'd Enclosure 9

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124015

Centre No. [][][][][]

Patient No. [][][][]

Initials **9550082**

Visit/cycle DAY [][][]

Date [][][] [][][] [][][]
D M Y

7. Pessimistic thoughts

- Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

No pessimistic thoughts [0]; fluctuating ideas of failure, self-reproach or self-depreciation [1]; Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future [2];

Delusions of ruin, remorse and unredeemable sin. Absurd self-accusations [3].

8. Concentration difficulties

- Representing difficulties in collecting one's thoughts amounting to incapacitating lack of concentration.

- Rate according to intensity, frequency, and degree of incapacity recorded.

- Distinguish from failing memory and disrupted thought.

No difficulties in concentrating [0]; Occasional difficulties in collecting one's thoughts [1]; Difficulties in concentrating and sustaining thoughts which interfere with reading or conversation [2]; Incapacitating lack of concentration [3].

9. Reduced sleep

- Representing a subjective experience of reduced duration or depth of sleep compared to the subject's own fitful sleep.

Sleep as usual [0]; Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep [1]; sleep reduced or broken by at least 2 hours [2]; Less than two or three hours sleep [3].

10. Reduced appetite

- Representing the feeling of a loss of appetite compared with when well.

Normal or increased appetite [0]; Slightly reduced appetite [1]; No appetite. Food is tasteless. Need to force oneself to eat [2]; Must be forced to eat. Food refusal [3].

Total score [][][]

596

Investigator's signature _____

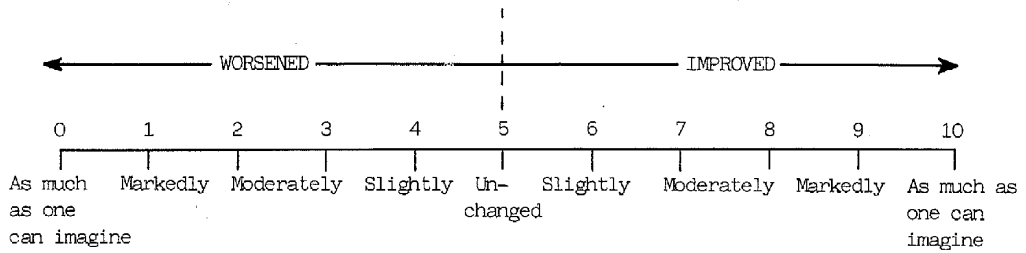
FARMITALIA CARLO ERBA
Erbamont group
R & D, CNS Line

9550082

Enclosure 10

PATIENT GLOBAL IMPRESSION

FROM STUDY START MY GENERAL CONDITIONS ARE:



By using this visual-analogue scale, please write the number corresponding to your actual situation.....

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Enclosure 11
Protocol No. |2|0|1|2|4|0|1|5|

Centre No. | | | | |

Patient No. | | | | |

9550082 Initials | | | | |

Visit/cycle |D|A|Y| | | |

Date | | | | |
D M Y

R.D.R.S.: RELATIONAL DEPRESSION RATING SCALE

Maurice OHAYON, 1985

SCORING INSTRUCTIONS

The scoring should be based upon the clinical interview as a whole, resorting to subjective observations rather than to specific questioning and/or medical history. The clinician should spot the clues indicating the patient's social withdrawal and loss of interest in other people, a characteristic feature of the depressive condition, through the impairment of the clinician/patient relationship.

The relational viewpoint in non-verbal communications: the patient's outward appearance (clothes, grooming, body gestures) allows the evaluation of the relational dynamics, apart from the patient's verbal complaints.

I. Facial expression

- 0 - The mimics fits in well with the speech, emphasizing emotions. The subjects smiles at the clinician or clearly expresses his feelings.
- 1 - The subject appears sometimes absent-minded, but quickly regains attention as soon as the clinician enlivens the interview. He smiles easily when stimulated.
- 2 - The patient does not smile. The mimics is poor, stereotyped. The patient gets lively only if stimulated.
- 3 - The patient's face hardly lits up, and this only under strong stimulation.
- 4 - The patient is completely unconcerned. The face is motionless, set, expressionless.

II. Body gestures

- 0 - Patient's bearing and movements are in keeping with speech. The posture is lithe, the patient makes himself comfortable in the chair.
- 1 - The patient exhibits some awkwardness, slightly shrinking or stooping. He/She sits ont he chair's edge. The patient gets progressively livelier in the course of the interview.
- 2 - The patient has a set expression, his movements involve the limbs only and not the rest of the body and are not harmonized with the speech. These features poorly improve during the interview.
- 3 - Heavily reduced motion, involving hands only. Movements and speech are not, or badly, in tune. Gestures are mechanical, stereotyped.
- 4 - Complete inertia. The posture is frozen, the back bent; the patient may fold up on the couch. He/She hardly speaks and is completely motionless.

III. Look

- 0 - The patient has keen, mobile eyes, exploring the room and making the eye-contact with the clinician. His/Her look is harmonized with speech and emotions.
- 1 - The patient looks around quite slowly, stares at the clinician and, from to time in the course of the interview, at unimportant objects.
- 2 - Patient's eyes are shifty, avoiding the clinician's eyes. At times, be stares into space.
- 3 - The patient hardly looks at the clinician unless stimulated.
- 4 - The patient has a dull, absent look, be stares into space and eyes are half- of fully closed.

IV. Outward appearance

- 0 - The patient is well groomed. His clothes reflect his desire to please, even some stylishness. He has proper clothes, hairdo and makeup.
- 1 - The patient's bearing betrays some carelessness, he seems unconcerned with his physical condition or, on the contrary, excessively stylish.
- 2 - The patient is disheveled and slovenly dressed; he rather keeps on his night clothes.
- 3 - The patient neither washes nor combs his hair or gets properly dressed, unless stimulated.
- 4 - The patient is absolutely unable to get dressed without help. He is completely unconcerned.

598

Investigator's signature _____

Cont: d Enclosure 11

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|5

Centre No. _____

Patient No. _____

Initials: _____
9550082

Visit/cycle D|A|Y| |

Date | | | | | | | | | |
D M Y

The relational viewpoint in verbal communications. Throughout the interview, the clinician should pay attention to the "relational" features of patient's speech: voice, flexibility, variety of topics should reflect the patient's ability to establish social relations.

V. Speech

- 0 - The patient has a broad and rich choice of topics, with covers family life, work, hobbies, friends, etc. The patient is interested in both the interview and the clinician.
- 1 - The patient's variety of topics is poorer. He is only concerned with his family, job, somatic complaints or his current illness.
- 2 - The subjects is interested only in few topics.
- 3 - The patient is wholly unconcerned about his surroundings. His choice of topics is poor, limited and repetitive.
- 4 - The patient is completely unconcerned with the outside world.

VI. Voice

- 0 - Voice's level and modulation are normal. Speech is fluent. Voice and speech are well harmonized.
- 1 - The voice is somewhat monotonous: speech slackens.
- 2 - The voice is monochord, low-pitched, speech is slow and interrupted by long breaks.
- 4 - The patient's speech is scarcely audible or monosyllabic.

VII. Adaptability, suggestibility

- 0 - The patient's answers, his whole behavior are matching to the situation. He/She reacts quickly when stimulated and follows the suggestions.
- 1 - The subject exhibits a slight sluggishness during the interview: he/she reacts a bit slowly, switching from one subject to the next quite reluctantly.
- 2 - The subject's thinking process is definitely sluggish: dulled ability to feel, to experience emotions. Reactions are slow and poorly improved by stimulations from the clinician. Fears and avoids the new experiences.
- 3 - Severe emotional withdrawal, reflexed by the patient's lack of interest in the present situation, the future, treatment, etc.
- 4 - Patient's adjustment to reality is nil. He/She feels quite cut off from the outside world and makes no attempts at communicating.

The relational viewpoint in affects: during the interview, depressive patients usually exhibit anxious and/or aggressive feelings. The rating should take them into account insofar as they impair the relations with the others or even hinder any self-expression. Guilt and self-aggression should be considered insofar as they allow or prevent the patient from calling on others for help.

VIII. Contacts, affective need

- 0 - The patient/clinician relationship is easily established, the patient is effusive, outgoing or even pushy.
- 1 - The patient exhibits a slight reserve, by no means pathological.
- 2 - The patient is reserved, aloof, shy, but gets progressively livelier in the course of the interview.
- 3 - The patient is withdrawn, self-concerned, avoids contact.
- 4 - No patient/clinician relationship can possibly be established.

IX. Anguish, anxiety

- 0 - The patient shows little or no anxiety during the interview. Anxiety arises in response to specific situations and is freely expressed through speech, voice and movements.
- 1 - The patient is plainly anxious during the interview and shows it through speech, posture and mimics.
- 2 - The patient actually complains of fear and anxiety: he seeks help and comfort. Somatic symptoms are more or less severe.
- 3 - The patient manifests strong anxiety throughout the interview, though he might express it badly. His complaints are vague, indefinite.
- 4 - The patient suffers from extremely severe anxiety, manifested by restlessness or nearly complete motionlessness. He/She is unable to verbalize his/her anxiety.

599 Investigator's signature _____

Cont. 'd Enclosure 11

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|5

Centre No.

Patient No.

9550082

Visit/cycle D|A|Y|

Date
 D M Y

X. Aggression, irritability

- 0 - The patient exhibits no aggression in his social relationships or aggressivity arising in response to peculiar conditions.
- 1 - The patient is irritable at times; he/she cannot easily endure minor everyday conflicts and will ascribe this to overtiredness.
- 2 - The patient is obviously irritable and hostile. He/She tends to reject the others. He/She ascribes his irritability to other people's aggressiveness or unreasonable demands.
- 3 - The patient is definitely aggressive. He sees the interview as intrusive and distressing, maintains a stubborn silence or utters aggressive claims. Contacts with close relations are felt as unduly distressing.
- 4 - The patient perceives human relations as distressing, intrusive, unbearable; he refuses to speak and to communicate.

XI. Self-aggression

- 0 - The patient easily communicates with other people, is able to endure minor aggressions and to react appropriately.
- 1 - Occasional awkwardness and anxiety, when the patient should be aggressive or authoritarian. He will try and avoid such situation and would rather bottle up his anger.
- 2 - Aggressions cause the patient anguish and intense guilt. Somatic symptoms are present.
- 3 - Severe self-aggression; suicidal ideas or plans, severe somatic symptoms or overwhelming unjustified guilty feelings.
- 4 - Delusional shamefulness or guilt, suicidal plans or acts.

The relational viewpoint in the patient/clinician relationship.
The scoring should take into account the clinician's subjective evaluation of the patient/clinician relationship and of the patient's relational skills in the course of the interview.

XII. Global evaluation

- 0 - Relationship are easily and freely established, in keeping with the situation.
- 1 - Slight aloofness, hardly perceptible.
- 2 - Obvious withdrawal; the relationship is eventually established after an initial phase of mistrust and reserve.
- 3 - Severe withdrawal, difficult relationship. The patient refuses contact.
- 4 - The patient/clinician relationship can hardly be established.

Could you suggest one or two items which are missing in the Relational Scale according to you.

ITEM No. 1: Title:

- 0 -
- 1 -
- 2 -
- 3 -
- 4 -

ITEM No. 2: Title:

- 0 -
- 1 -
- 2 -
- 3 -
- 4 -

600

Investigator's signature _____

Farmitalia Carlo Erba

Erbaont Group

ENCLOSURE 13

Corporate Medical Coordination

9550082

ADVERSE DRUG REACTION - A CRITICAL REVIEW

CAUSE-EFFECT RELATIONSHIP

F.E.KARCH, L.LASAGNA
(JAMA Dec. 22, 1975-Vol.234)

1. DEFINITE (or CERTAIN)

A reaction that follows a reasonable temporal sequence from administration of the drug or in which the drug level has been established in body fluids or tissues; that follows a known response pattern to the suspected drug; and that is confirmed by improvement on stopping the drug (dechallenge), and reappearance of the reaction on repeated exposure (rechallenge).

2. PROBABLE

A reaction that follows a reasonable temporal sequence from administration of the drug; that follows a known response pattern to the suspected drug; that is confirmed by dechallenge; and that could not be reasonably explained by the known characteristics of the patient's clinical state.

3. POSSIBLE

A reaction that follows a reasonable temporal sequence from administration of the drug; that follows a known response pattern to the suspected drug; but that could have been produced by the patient's clinical state or other modes of therapy administered to the patient.

4. DOUBTFUL

Any reaction that does not meet the criteria above.

5. UNKNOWN

Relationship for which no evaluation can be made.

6. NOT RELATED

A reaction for which sufficient information exists to indicate that the aetiology is unrelated to the study drug.

Enclosure 14

FARMITALIA CARLO ERBA
Erbamant Group

Compound **REBOXETINE**

Protocol No. 201240115

Centre No. _____

Patient No. _____

Initials **9550082**

Visit cycle D A Y _____

Date _____
D M Y

ADVERSE EVENT REPORT FORM*

1. DESCRIPTION/DURATION

WHO CODE _____

Adverse event (verbatim): _____

Report 1: Onset date: Still present: End date:

1 spontaneously / / 1 no 2 yes / /

2 non-leading question

3 check list single episodes duration d _____ or hr _____ or min _____

case of multiple episodes, give mean duration d _____ or hr _____ or min _____

2. CHARACTERIZATION

Severity:	Source:	Frequency:	History:
1 <input type="checkbox"/> mild	1 <input type="checkbox"/> physician	1 <input type="checkbox"/> single episode	1 <input type="checkbox"/> observed before the current treatment
2 <input type="checkbox"/> moderate	2 <input type="checkbox"/> patients	2 <input type="checkbox"/> continuous	2 <input type="checkbox"/> not observed before
3 <input type="checkbox"/> severe	3 <input type="checkbox"/> other specify _____	3 <input type="checkbox"/> multiple episodes.	3 <input type="checkbox"/> unknown
4 <input type="checkbox"/> unknown		specify No. of episodes: _____	

3. ACTION TAKEN

Hospitalization:	Study drug:	Other actions:
1 <input type="checkbox"/> required	1 <input type="checkbox"/> no change	1 <input type="checkbox"/> discontinuation of other medication (if yes, fill in the form about medication at page 1)
2 <input type="checkbox"/> not required	2 <input type="checkbox"/> dose reduced	2 <input type="checkbox"/> Symptomatic treatment (if yes, fill in the form about medication at page 1)
3 <input type="checkbox"/> not applicable	3 <input type="checkbox"/> definitively withdrawn	
	4 <input type="checkbox"/> temporarily interrupted.	
Code opened:	specify No. of days _____	3 <input type="checkbox"/> other action: _____
1 <input type="checkbox"/> no 2 <input type="checkbox"/> yes		

* **FILL IN ONE FORM BY SINGLE EVENT** (if serious or unexpected promptly inform the Study Monitor)

603 Investigator's signature _____

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

Enclosure, 15

9550082

**Appendix 5
Declaration of Helsinki IV (Hong Kong - September 1989)**

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Recommendations guiding physicians
in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly,
Helsinki, Finland, June 1964,

and amended by the
29th World Medical Assembly,
Tokyo, Japan, October 1975,
35th World Medical Assembly,
Venice, Italy, October 1983
and the
41st World Medical Assembly
Hong Kong, September 1989

INTRODUCTION

It is the mission of the physician to safeguard the healthy of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient." The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

9550082

1. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Physicians should abstain from engaging in research projects involving human subject unless they are satisfied that the hazard involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazard of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.
12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE
(Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient of participate in a study must never interfere with the physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).
6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

FARMITALIA CARLO ERBA
ERBAMONT GROUP
CNS LINE

9550082

Enclosure 16

LIST OF MONITORS

No.	Country	Monitor (Address)
1.	Australia	Dr. R. Degaris 765 Glenferrie Road Hawthorn, Vic. 3122 phone: (61-3) 8192900 fax: (61-3) 8192469
2-6.	France	Dr. M. Bosc 100, Av. Albert 1 ^{er} , B.P.203 92502 Ruel Malmaison Cedex phone: (31-1) 47142200 fax: (31-1) 47496658
7.	Germany	Dr. I. Götz-Lee Merzhauser Str. 112 Postfach 480 7800 Freiburg in Breisgan phone: (49-761) 4013125 fax: (49-761) 4013199
8-9.	Italy	Dr. S. Tazzari via C.Imbonati 24 20159 Milano phone: (39-2) 69952749 fax: (39-2) 69952249
10.	Sweden	Dr. G. Wedin Alvägen 5, Box 3511 183 03 TÄBY phone: (46-8) 7567085 fax: (46-8) 7568247
11.	United Kingdom	Dr. J. Powell Italia House 23 Grosvenor Road St. Alban's, Herts. AL1 3AW phone: (44) 72740290 fax: (44) 72740290
12.	Canada	Dr. S. Gupta Adria Laboratories 5476 Gorvan Drive, Mississauga Ont. L4W 3E8 phone: (416) 6254552, fax: (416) 6256801

20124/015

Date: September 19, 1990

FARMITALIA CARLO ERBA
ERBAMONT GROUP
CRS LINE

Enclosure 17

9550082

DRUG ACCOUNTABILITY

Compound: REBOXETINE

Protocol N°: 20124/015

Title: Multicenter, multinational double-blind study of the activity and tolerability of Reboxetine vs Imipramine vs Placebo in patients suffering from Major Depressive Episodes

Centre N°/City _____ Investigator: _____

Treatment received: | | | | for patient N° _____ to patient N° _____ Receipt N° _____
d m y

Bottles per patient received: 14 + 6 (dose 2)

Pat N°	Pat. Init.	Date Start	Weekly treatment given	N° of remaining bottles per pat.	N° of remaining caps. per pat.
			1__ 2__ 3__ 4__ 5__ 6__ Dose 2: 4__ 5__ 6__	__ + __ (dose 2)	__ + __ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ Dose 2: 4__ 5__ 6__	__ + __ (dose 2)	__ + __ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ Dose 2: 4__ 5__ 6__	__ + __ (dose 2)	__ + __ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ Dose 2: 4__ 5__ 6__	__ + __ (dose 2)	__ + __ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ Dose 2: 4__ 5__ 6__	__ + __ (dose 2)	__ + __ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ Dose 2: 4__ 5__ 6__	__ + __ (dose 2)	__ + __ (dose 2)


N° of total caps. to be returned: _____

N° of total bottles to be returned: _____

Date: _____

Investigator's signature _____

- ♦ The present form, duly filled out, should be kept as record by the investigator, together with his/her copy of CRFs.
- ♦ A photocopy of the present form should be given to the monitor of Farmitalia Carlo Erba, together with the unused drug at the end of the study.

 **ITALIA ASSICURAZIONI**

9550082

Enclosure 18

Milano 11/01/90/GF

Spett.Le
FARMITALIA CARLO
ERBA S.R.L.
Via C. Imbonati 24

20159 MILANO

DICHIARAZIONE
DECLARATION
To whom it may concern

La sottoscritta ITALIA Assicurazioni S.p.A. con sede in Genova -Via Fieschi 9 -
THE UNDERSIGNED ITALIA Assicurazioni S.p.A., with head office in Genoa, Via Fieschi 9,

dichiara a tutti gli effetti che la Spett.le FARMITALIA CARLO ERBA SRL
hereby declares to all intents and purposes that the firma FARMITALIA CARLO ERBA SRL

con sede in Milano - Via C. Imbonati 24 e' assicurata contro la
with head office in Milan - Via C. Imbonati 24, is insured against

responsabilita' civile verso terzi per danni derivanti dalla sua attivita' (ivi compresa "produzione"
third party liability for damage deriving from their activities (including "production"

e "smercio") e dalle sue proprieta' con polizza n.4w8102, scadente il 31.12.1990
and "sales") and its properties, under policy No.4w8102, expiring on 31.12.90

e tacitamente rinnovabile di anno in anno, per il massimale unico
di L. 10.000.000.000.=(diecimiliardi) per sinistro
automatically renewable for one year at a time, to cover up
to L.10.000.000.000 (ten thousand million Lire) as a single anyone claim,

nei termini tutti di cui alla polizza stessa.
in all terms concerning the policy itself.

La garanzia e' valida per il mondo intero e prevede, tra l'altro, anche l'estensione della copertura ai seguenti:
This coverage is applicable through out the world, and includes the following: =

- danni causati da specialita' medicinali e prodotti medicinali che secondo la
- damage arising from medicinal specialities and products which, according to

comune prassi, prima della loro registrazione sanitaria e della loro
normal practice, before they are officially registered and

immissione in commercio, vengono consegnati a cliniche, ospedali,
put on the market, are giving to clinics, hospitals

case di cura ed esercenti professioni sanitarie per sperimentazioni e
nursing homes and professional health workers for clinical trials and

610



Italia assicurazioni spa sede legale 16121 Genova via Fieschi 9 capitale sociale L. 30.000.000.000 trib. Genova 101 cciaa 30488
autorizzata all'esercizio delle assicurazioni (art. 85 r.d.l. 986/29-4-28) c.f. 00432690105

 **ITALIA ASSICURAZIONI**

9550082 Enclosure 18 cont'd

prove cliniche, nonché ai danni causati a seguito di somministrazione
tests and damage arising following administration for pharmacological tests

per ricerche di farmacologia ed esperimenti con farmaci e preparazioni già registrate in Italia
experiments of drugs or preparations already registered in Italy

e/o all'estero, ma con posologie diverse da quelle
and/or in other countries but using dosages different from these

indicate dalle case produttrici e con nuovi farmaci in fase di studio;
indicated by the manufacturer and of new drugs in the study stage;

comprese tutte le attività inerenti e connesse alle sperimentazioni stesse,
including all activities connected with and inherent to tests and trials

quali la tecnica di somministrazione dei farmaci ed il prelievo dei
such as the methods of administering drugs and withdrawing

sangue dai soggetti per studio; il tutto con prodotti
blood samples from subjects under study; all with products

sia ad uso umano che non, propri e/o di terzi;
for human use or not, own and/or of the third party.

- connessi a responsabilità civile che possa derivare personalmente
- damage relating to third party liability which may result personally

agli sperimentatori sia nel paese dell'Assicurata che all'estero
to the experimenters both in the country of Insured and/or in other countries

in ragione degli esperimenti effettuati su richiesta e/o per conto dell'Assicurata stessa.
because of the experiments effected at request and/or for account of the Insured.

La presente viene rilasciata a richiesta della Spett.le FARMITALIA CARLO ERBA SRL
This declaration is issued in response to a request by FARMITALIA CARLO ERBA SRL

Relativamente alla presente dichiarazione redatta sia in lingua italiana che in
Relatively to the present declaration drawn up both in Italian language and

lingua inglese, viene convenuto che, in caso di divergenza tra i due testi,
English language, it is agreed that, in case of divergence between the two texts,

Mod. 96/102 P. - 7/88 - CHIESTA-GENOVA

611

2



Italia assicurazioni spa sede legale 16121 Genova via Fieschi 9 capitale sociale L. 30.000.000.000 trib. Genova 101 cciaa 30488
autorizzata all'esercizio delle assicurazioni (art. 85 r.d.l. 966/29-4-23) c.f. 00432690105

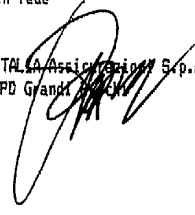
 **ITALIA ASSICURAZIONI**

9550082 Enclosure 18 cont'd

prevarrà, ai fini interpretativi, il testo in lingua italiana.
the one in Italian language will prevail for the purpose of interpretation.

In fede

ITALIA Assicurazioni S.p.A.
UPD Grandi



Mod. 99/082 P. 7/86 - CREDITO RENDITA

612



Italia assicurazioni spa sede legale 16121 Genova via Fieschi 9 capitale sociale L. 30.000.000.000 trib. Genova 101 cciaa 30488
autorizzata all'esercizio delle assicurazioni (art. 85 r.d.l. 968/29-4-23) c.f. 00432690105

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9550082

Attachment A

REBOXETINE PROTOCOL 20124/015: OPERATING PROCEDURES FOR TRAINING ON ASSESSMENT INSTRUMENTS, STUDY MONITORING AND COORDINATION.

Aim

The purpose of these procedures is to provide standardization of the study conduct in the different clinical centers and to assure data uniformity and compatibility by appropriate interventions during data gathering.

Inter-rater reliability

During the clinical trial:

- inter-rater agreement for the instruments used in the assessment of change (HAMD, RDRS) will be tested on the occasion of the first Investigator Meeting (2 videotaped interviews) and of the monitoring visits (2 videotaped interviews).

Study monitoring

During the course of the study (14-months) monthly monitoring visits will be conducted by Study Monitors from Farmitalia Carlo Erba.

The start-up visit will take place after approval of the protocol by the Institutional Review Board (IRB) or Ethical Committee. On this visit the following documents will be collected:

- copy of the protocol signed by the Principal Investigator;
- CV of Principal Investigator and Co-Investigators;
- the written approval of the study (typed on the Institute's letter head) by the Hospital or University Center Review Board and the IRB members list;

Prot. N° 20124/015⁹⁵⁵⁰⁰⁸² Cont. Attachment A

- an IRB approved blank copy of the consent form;
- the list of the laboratory normal values or ranges of the lab. tests.

These documents will be sent to FICE-Milan. On the occasion of this visit the monitor will also check that the CRFs and the drug supply have been delivered to the Clinical Investigator and the accompanying letter, signed by the Clinical Investigator, will be collected. In addition the Monitor will identify the staff members who will be involved in the study conduct and the monitoring visits schedule will be agreed.

Following the start-up visit the form A (enclosed) will be filled in. Copy of it will be sent to FICE in Milan.

The first monitoring visit will be done immediately after the recruitment of the first two, three patients.

The periodic monitoring visits are carried out in order to:

- 1 verify protocol adherence: patient eligibility (page 1 of the CRF), times of assessments, completeness of data, pill count;
- 2 verify data consistency looking for inconsistencies or errors in the data recorded on the CRF;
- 3 verify the accuracy of data collection in CRFs against the original clinic or hospital records for:
 - pt initials and hospital record no
 - signed informed consent
 - study medication administration and concomitant medications
 - physician notes on adverse events
 - 20% of data for laboratory tests, patient history and vital signs; in case of an error rate > 15% all data need to be monitored;
 - total Hamilton score reported in the hospital record.

Source-verified data can be initialled by the study monitor in the CRF.

- 4 review all adverse events including laboratory abnormalities, occurred since the previous visit. Should the information of a serious, or unexpected adverse event newly emerge, the local study Monitor

Prot. N° 2012/01982

Cont. Attachment A

must immediately (within two working days) inform the Product Leader in Milan;

- 5 evaluate patient recruitment rate and treatment discontinuations;
- 6 verify study medication storage and accountability and collect bottles of completed treatments;
- 7 ensure continued acceptability of the facilities and of the staff.

CRFs will be completed in black ink and corrections, if needed, made only by the Clinical Investigator with a single line throughout; the corrections will be initialled by Clinical Investigator and dated. Each page of each completed CRF will be signed by Clinical Investigator.

After review for accuracy and completeness, the original and first copy of each page of the CRF will be removed (leaving the second copy with the Investigator). The first copy will be sent to Milan by Special Delivery Service for review and data processing while the original will be retained by the Monitor in the subsidiary until completion of the whole treatment period of the individual patient.

After each monitoring visit the periodic site visit report and the patients progress report form (form B and C enclosed) will be filled in. Copy of them will be sent to FICE Milan.

The study termination visit will be performed upon Investigator's completion of all CRFs of treated patients. During this visit:

- 1 the monitor will check and collect the remaining completed CRFs and will perform a final data review;
- 2 a final check and review of drug accounting, inventorying of remaining drug supplies and arrangement to send them to FICE will be done;
- 3 a time frame for study reporting will be discussed;
- 4 appropriate follow-up of patients under long-term treatment will be assured and monitoring and collection of data from these patients discussed and agreed

The study termination visit form (form D) will be filled in and copy of it sent to FICE Milan.

Prot. N° 20124/015

9550082
Conf. Attachment A

Study coordination

In order to obtain uniformity and standardization in the carrying out of the study a Steering Committee is established. All questions arising during the conduct of the study will be submitted to the Committee for advice and action taking.

In particular the Committee will take care of:

- queries about patients acceptability
- possible need of protocol amendments
- possible need of premature termination of the study
- acceptability of particular cases of protocol violations
- evaluation of clinically relevant adverse events and their scientific and ethical consequences in terms of issues raised or study discontinuation.

Members of the Committee will be: Prof. T. Ban and Prof. M. Ohayon

Any problem or issue arising during the conduct of the study will be submitted to the Committee in writing by the Clinical Investigators or by the study Monitors. "Ad hoc" meetings of the Committee will be organized when needed. File note of the meeting with conclusions about action taking will be circulated to Clinical Investigators and study Monitors.

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ATTACHMENT C: ASSESSMENT OF COGNITIVE FUNCTION

BACKGROUND

Difficulties in concentration, slowing down of thought processes and indecisiveness are common during the depressive state (1); these cognitive symptoms are well defined on a clinical basis. Other cognitive aspects of depression refer to psychological constructs suggested by different psychological theories of depression (2); these aspects will not be considered in the present study.

In order to evaluate the cognitive deficit associated with depressive illness and the effect of treatment on it, a test is proposed based on the analogic model of the cognitive process (3), focused on the deficit of the processing of information.

The tests are aimed at stimulating the analogic power ability of the patient for the creation of the new rule of production of information.

ASSESSMENT INSTRUMENTS

Tests consist of a series of visual elements and the patient is asked to image the last element of the series, from previous elements information. The proposed model for the analysis of cognitive disorders is as follows:

- 1) If A> B
- 2) Then C?.....> D
- 3) What's the patient's opinion about the quality of his (her) reply, of his (her) degree of satisfaction with it?

The comprehension of the relation between A and B is related to the level of vigilance. Vigilance increases with low levels of anxiety, but decreases when the intensity of anxiety overshoots a threshold. In addition attention and vigilance are known to be disturbed in depressive disorders.

When the relation between C and D is obtained (in case of relation established, two alternatives are possible) the analysis of the reply of the patient allows the estimation of the severity of the depressive disorder and of patient adaptation reasoning ability.

The analysis of the patient opinion about the quality of the reply allows the evaluation of judgement ability of the patient.

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9550082 Cont. Attachment C

It can be hypothesized that in basal conditions and under placebo patients would poorly understand the relation between A and B. Imipramine is expected to have a negative effect on the learning process, whereas reboxetine is expected to improve the learning ability of the patient.

Moreover the correlation between presence of anticholinergic type side-effects and learning ability will be estimated, in order to test the hypothesis that anticholinergic properties are associated with modification of cognitive or memory performance.

The evaluation of cognitive disorder will be done manual at D 0, D 14, D-end. For each evaluation, a manual (Appendix 1) will be used in which several series of visual elements have been assembled. The patient will complete the empty rectangle and will reply to the questions.

Presence of dementia will be excluded at admission (score lower than 22 on MMS scale).

Presence of melancholia with inhibition is expected to prevent testing in extreme conditions. In this case the patient will be included in the study and the cognitive test will be administered again after the first week of treatment.

If the patient is not able to fill in the form, or refuse to fill it in, this has to be specified in the appropriate space with a comment to justify his (or her) attitude.

In addition in order to assess the correspondence between the new model and a more classic approach for the evaluation of cognitive function memorization ability will be evaluated according to Signoret (4-8) (evocation and recognition of figures) and vigilance explored according to Mesulam (7-9). For the Signoret test the score corresponds to the number of figures recognized (recognition) and memorized (evocation), while for the Mesulam test the score is represented by the number of recognized letters. Data will be collected in the appended exercise booklet (Appendix 2).

STATISTICAL CONSIDERATIONS

All randomized patients will be included in the analysis of cognitive function assessment.

This analysis will consider several aspects.

- Evaluation of relation between memory and cognitive disorders at D 0, D 14, D end.

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9550082 Cont. Attachment C

- Study of C_____D relation of cognitive process with rankin of the 2 possible responses and evaluation of the treatment effect on their frequencies.
- Study of judgement quality, evaluation of treatment influence according to treatment duration.
- Search for a correlation between judgement quality and depression rating scales scores.

The comparison between these qualitative data will be done by arm and by assessment interval by means of chi-square test. Correspondence analysis will be used for the evaluation of the possible correlation between cognitive function and depression rating scales and between cognitive function and anticholinergic-type side effects.

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Emotional, interpersonal, and cognitive components.
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COMPOUND :REBOXETINE

Prot.N°20124/015

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APPENDIX N°1

MANUAL FOR

COGNITIVE EVALUATION

Protocol n°

Center n°

Patient initial [][] n° [][]

Day of assessment [][]^D [][]

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EXPLANATIONS
(to be re d attentively):

We have just given you an exercise-book, in which you have to reply to a set of simple questions.

Each page is composed of one or two pictures.
Each picture comprises 4 rectangles.
In the first three rectangles (n° 1,2,3) you can see a figure, while the rectangle n° 4 is empty.

You have to find and write the figure in the rectangle n°4, which results from the rectangle n° 3 in using between the rectangle n° 3 and n° 4 the same relation which links the rectangle n° 1 and n° 2.

Below the picture, you have to tell if your reply seems correct or not, in expressing your opinion by crossing one of the 4 drawn squares after the question "Do you consider your answer to be :"

This exercise is not a test to evaluate your efficiency or your judgment capacity; there are several possible replies for each question, and all the answers are valid.

M.M.S. score only at Do:

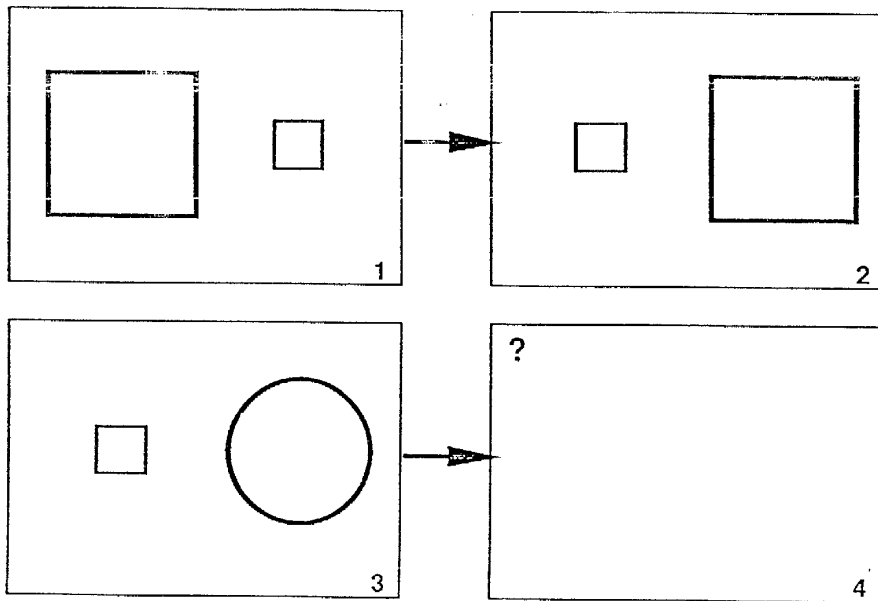
EXEMPLE

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(to fill only at Do, helping the patient)

If figure 1 becomes figure 2, what does figure 3 become ?

N A



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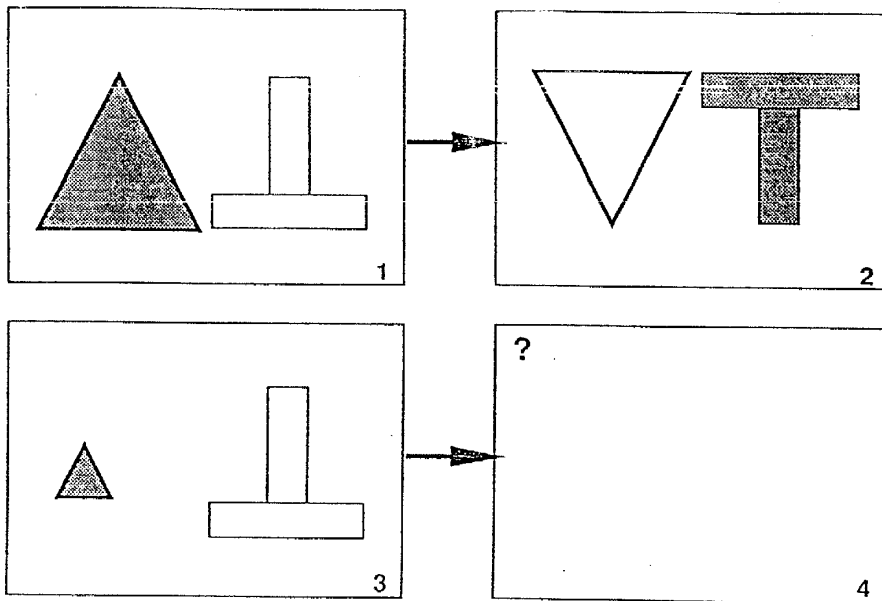
Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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You don't must come back to the prior page.
(Use a ball-point pen and no a pencil; you can do deletions.

If figure 1 becomes figure 2, what does figure 3 become ?

N B



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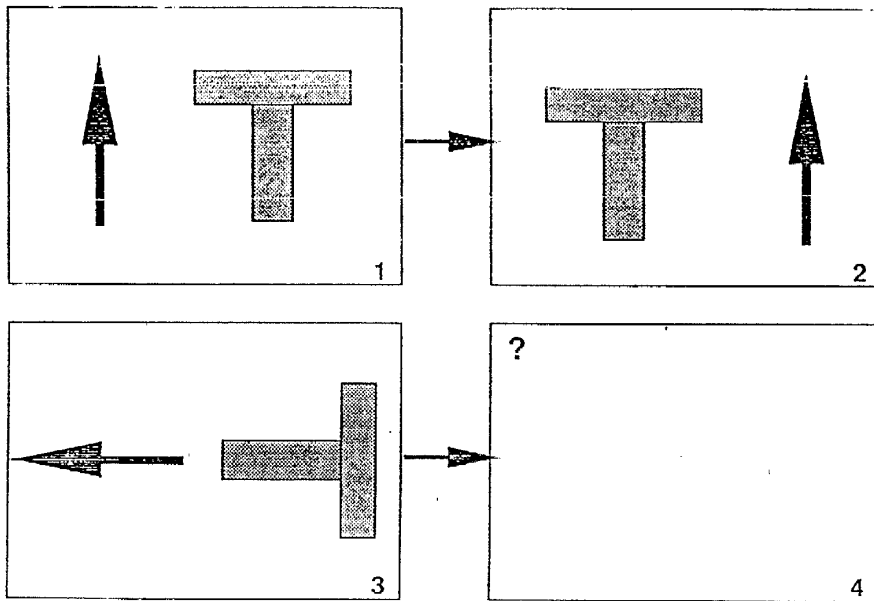
Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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If figure 1 becomes figure 2, what does figure 3 become ?

N C



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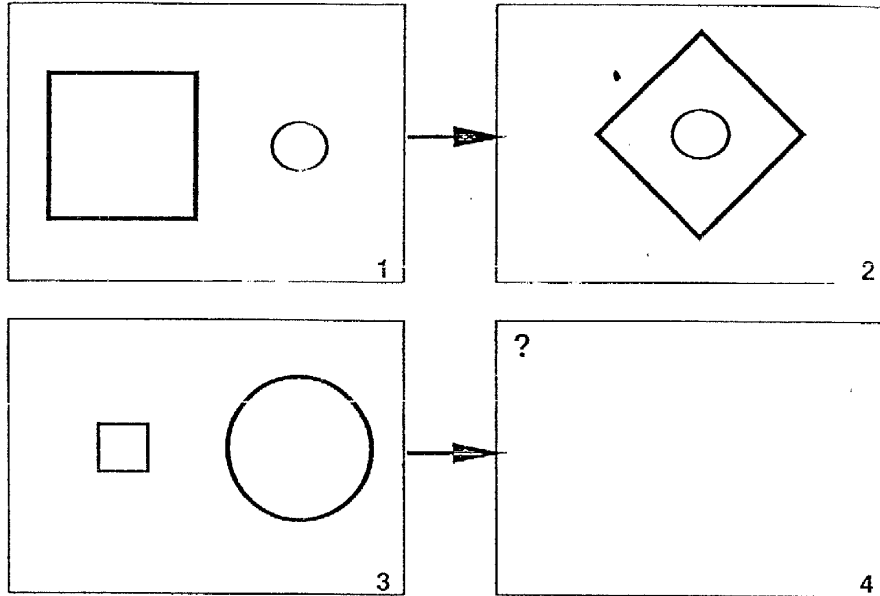
Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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If figure 1 becomes figure 2, what does figure 3 become ?

N 1



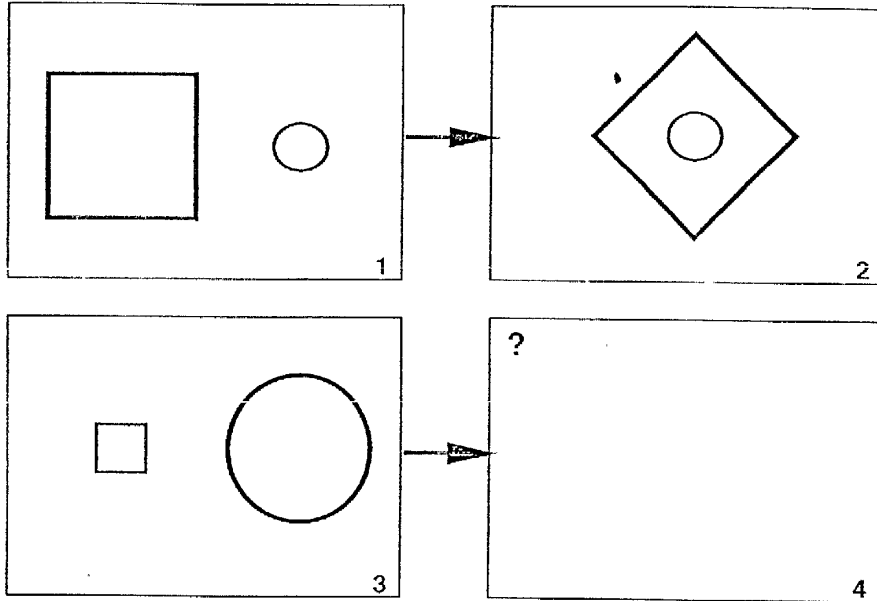
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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

9550082

If figure 1 becomes figure 2, what does figure 3 become ?

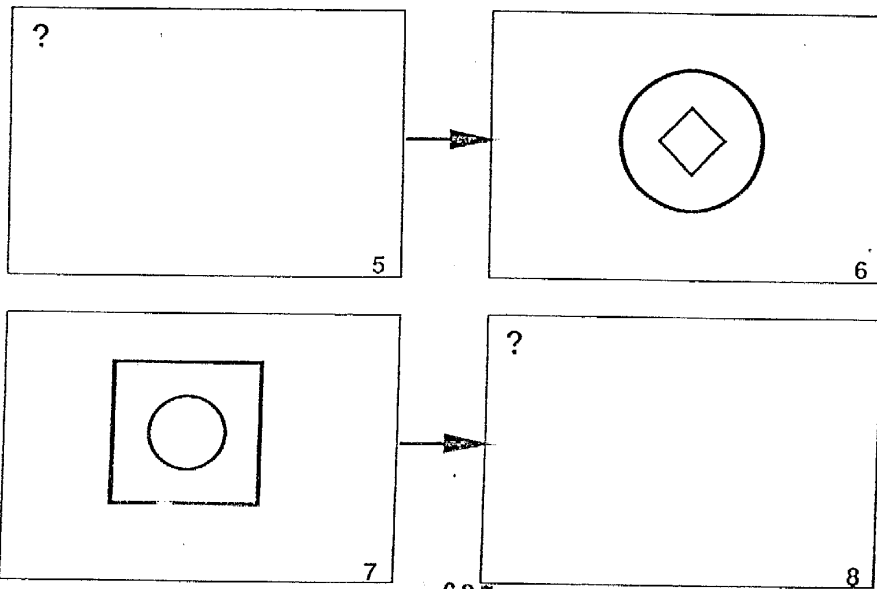
N 1



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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

If the result (figure 4) becomes figure 6, what does figure 7 become ?



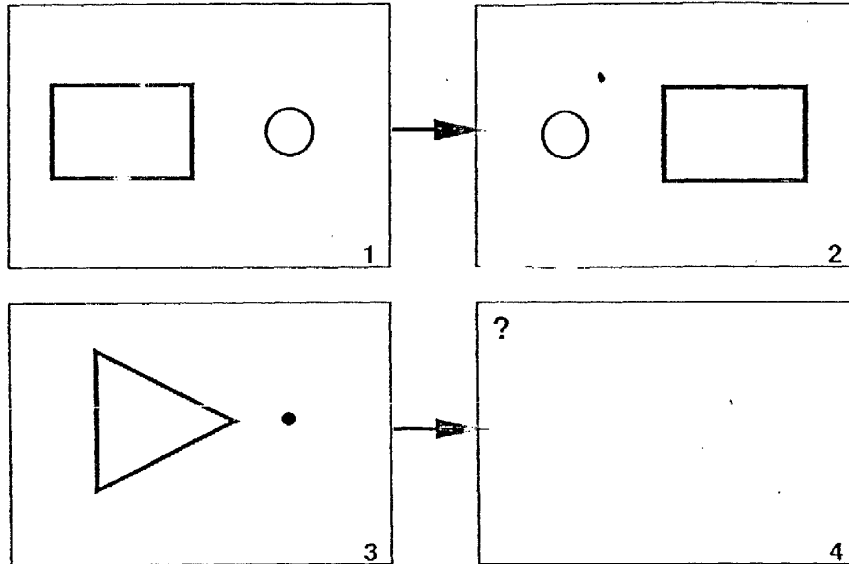
627

Do you consider your answer to be : VERY GOOD GOOD Medium POOR

9550082

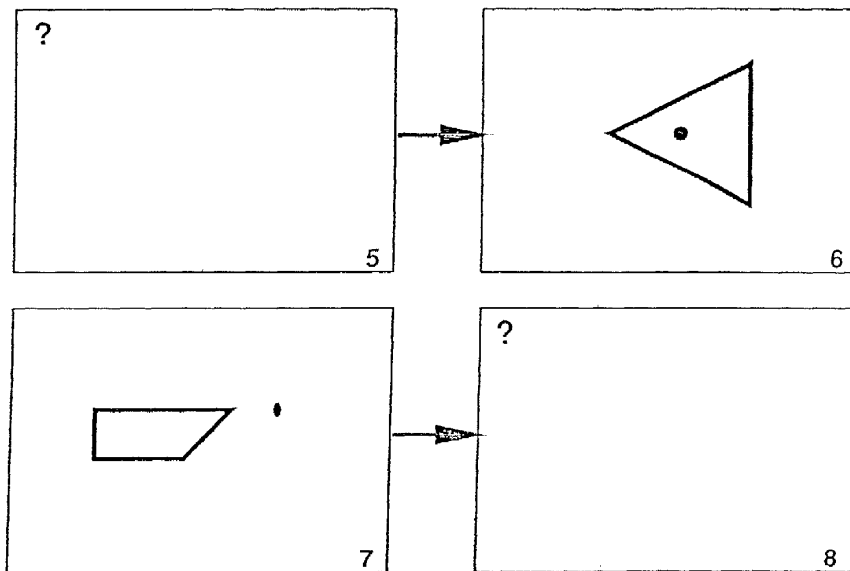
If figure 1 becomes figure 2, what does figure 3 become ?

N 3



Do you consider your answer to be : VERY GOOD GOOD Medium POOR

If the result (figure 4) becomes figure 6, what does figure 7 become ?

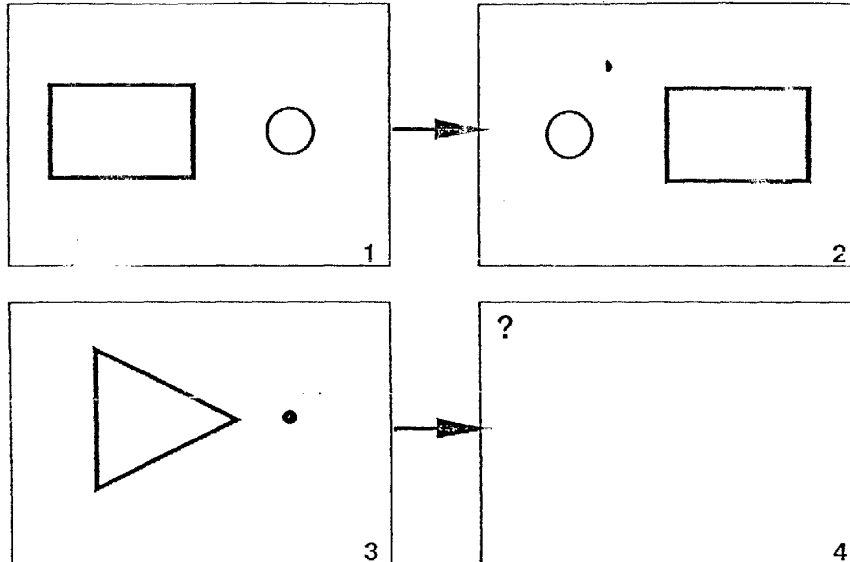


Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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If figure 1 becomes figure 2, what does figure 3 become ?

N 3

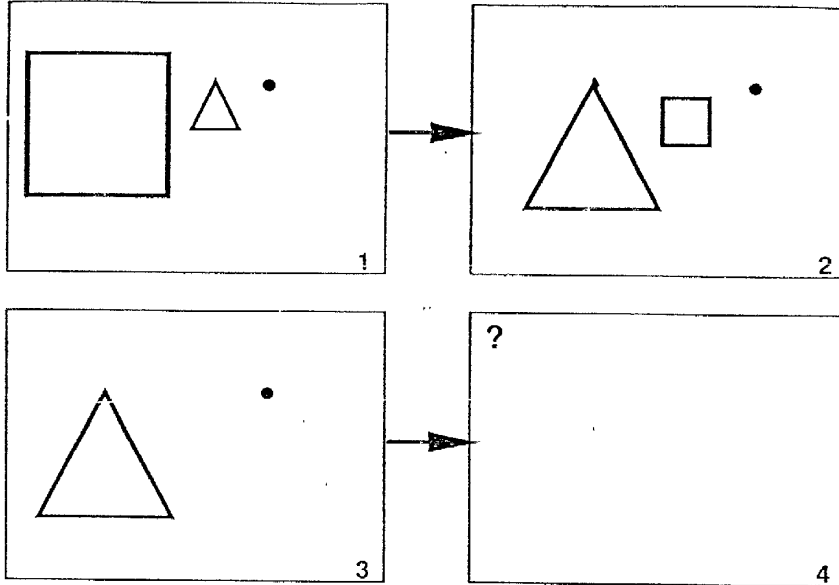


Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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If figure 1 becomes figure 2, what does figure 3 become ?

N 4



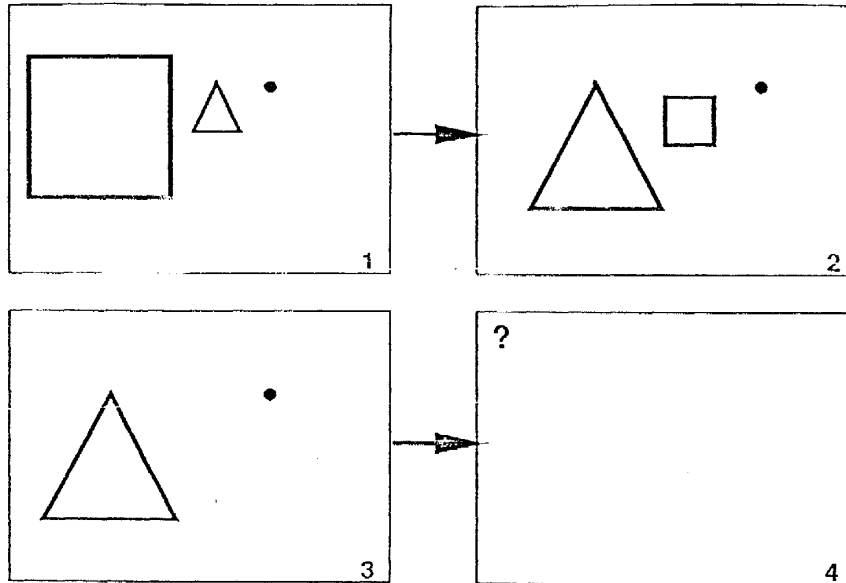
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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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If figure 1 becomes figure 2, what does figure 3 become ?

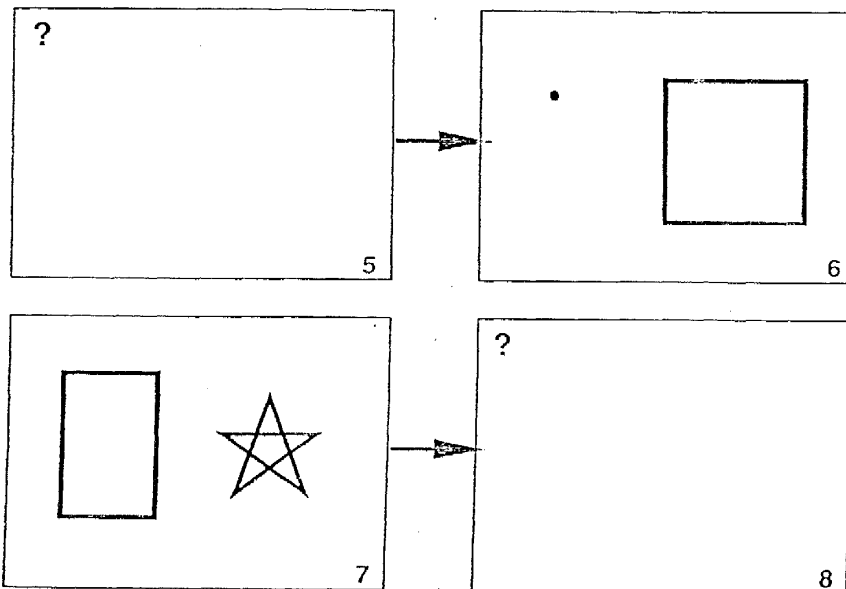
N 4



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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

f the result (figure 4) becomes figure 6, what does figure 7 become ?



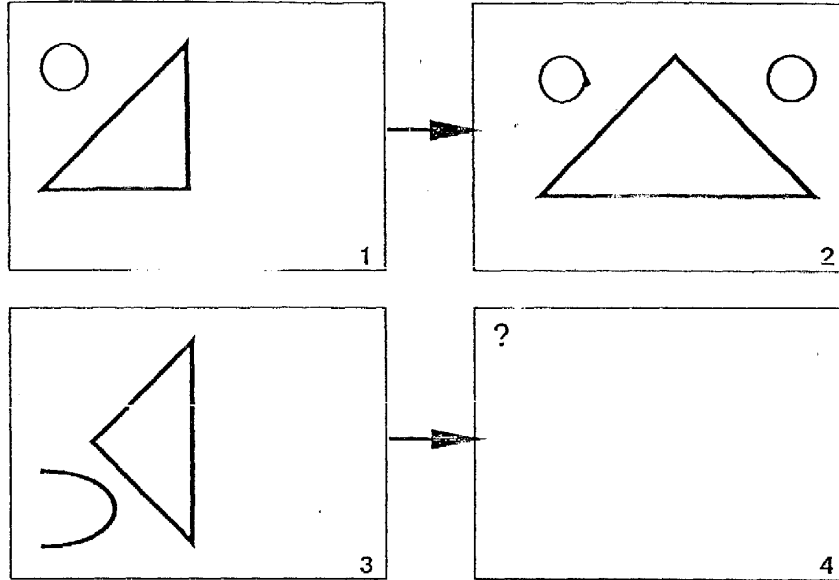
Do you consider your answer to be : VERY GOOD GOOD Medium POOR

631

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If figure 1 becomes figure 2, what does figure 3 become ?

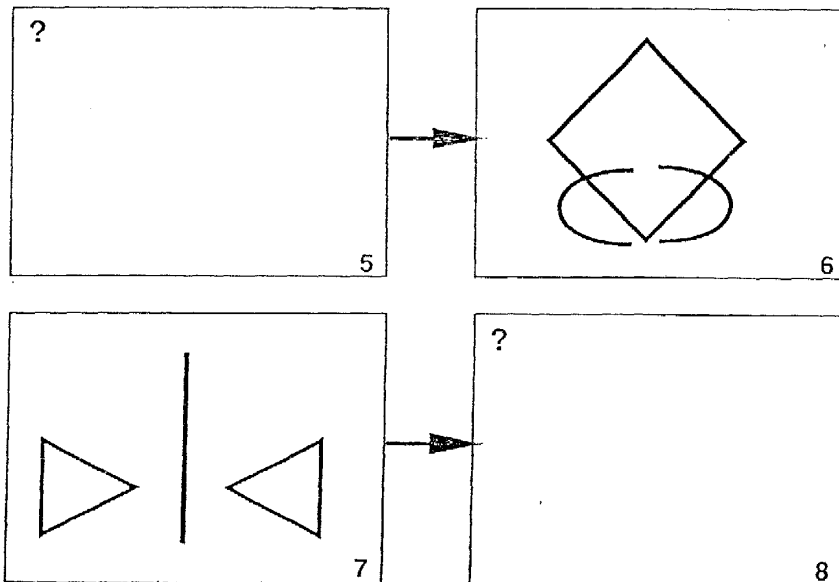
N₅



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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

If the result (figure 4) becomes figure 6, what does figure 7 become ?



Do you consider your answer to be : VERY GOOD GOOD Medium POOR

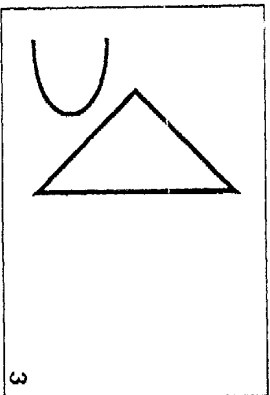
632

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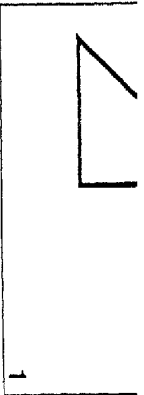
Do you consider your answer to be :

VERY GOOD GOOD Medium POOR

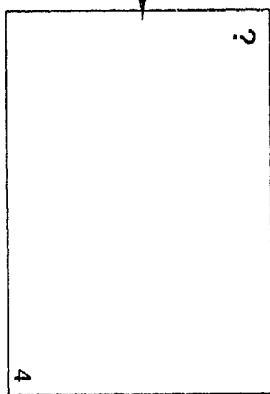
3




1



4



2

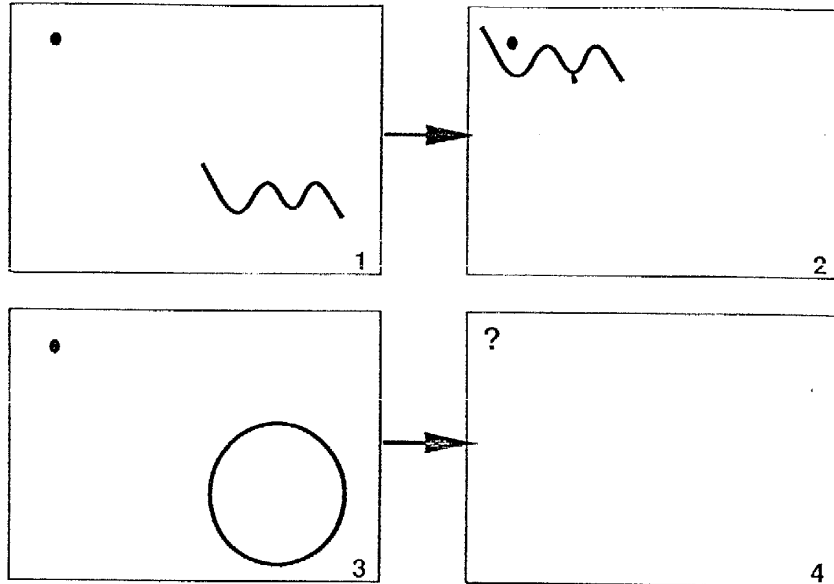


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If figure 1 becomes figure 2, what does figure 3 become ?

N 6



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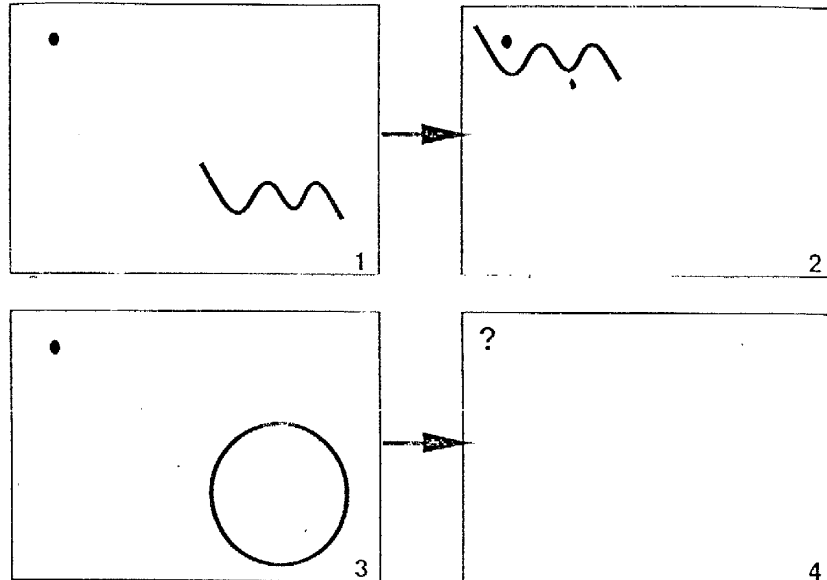
Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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If figure 1 becomes figure 2, what does figure 3 become ?

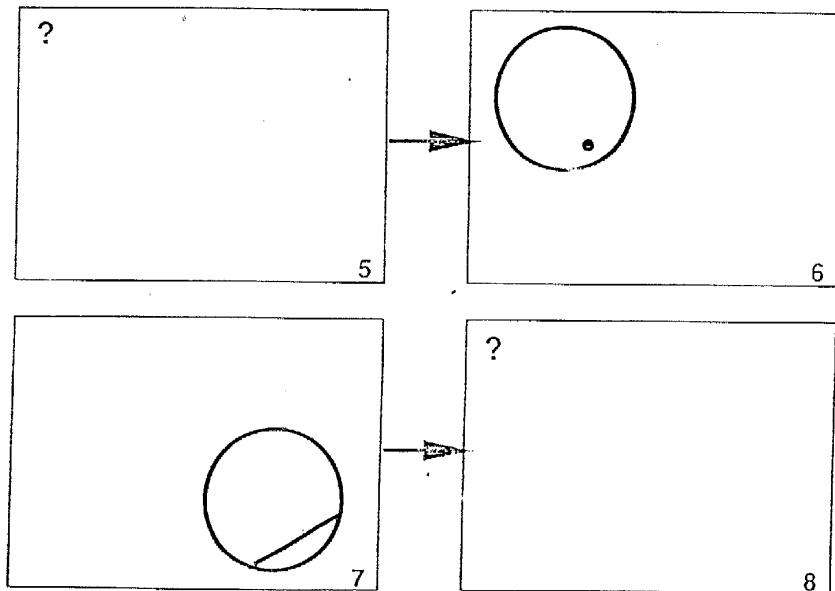
N 6



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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

If the result (figure 4) becomes figure 6, what does figure 7 become ?



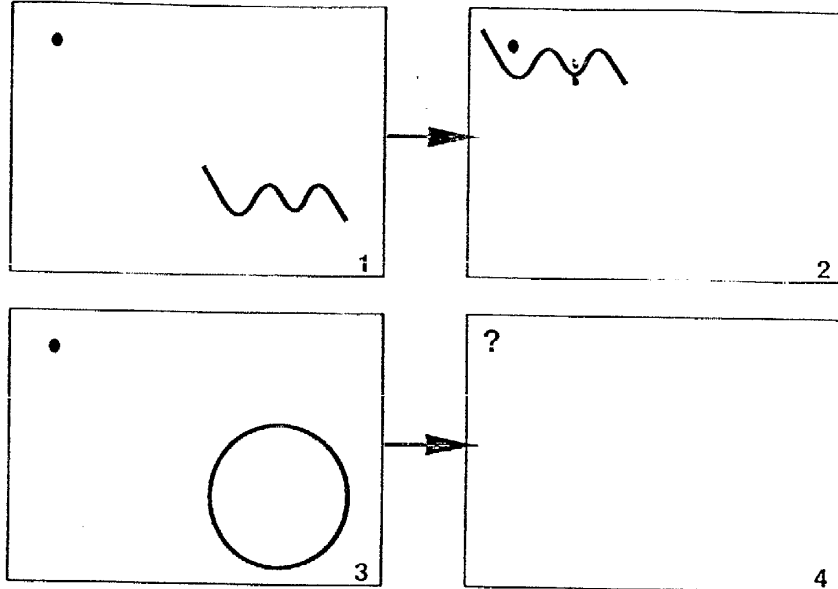
Do you consider your answer to be : VERY GOOD GOOD Medium POOR

635

9550082

If figure 1 becomes figure 2, what does figure 3 become ?

N 6



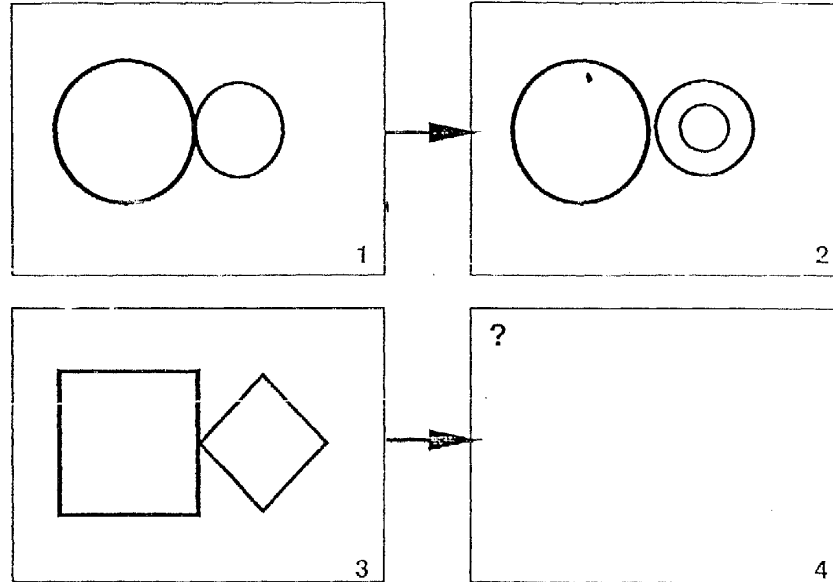
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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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If figure 1 becomes figure 2, what does figure 3 become ?

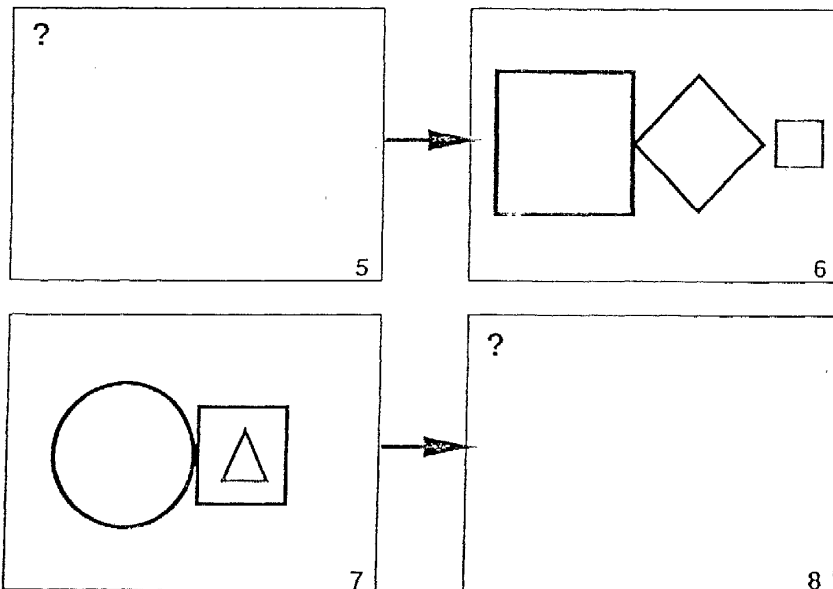
N 10



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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

f the result (figure 4) becomes figure 6, what does figure 7 become ?



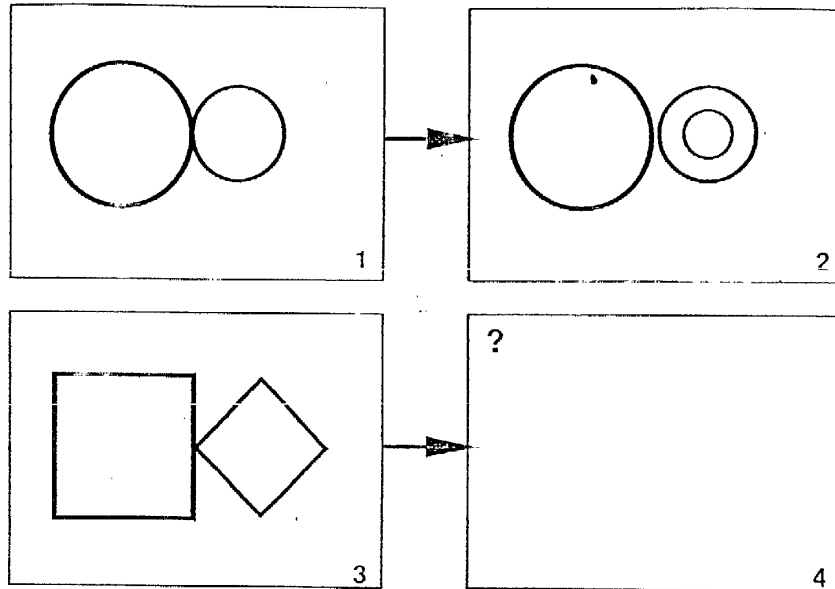
Do you consider your answer to be : VERY GOOD GOOD Medium POOR

637

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If figure 1 becomes figure 2, what does figure 3 become ?

N 10



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Do you consider your answer to be : VERY GOOD GOOD Medium POOR

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COMPOUND :REBOXETINE

Prot.N°20124/015

APPENDIX N°2

MANUAL FOR

MEMORY ASSESSMENT

Center n°

Patient initial n°

Day of assessment
D

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MEMORY TEST
(According to Signoret)

EVOCATION

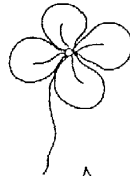
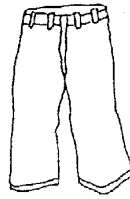
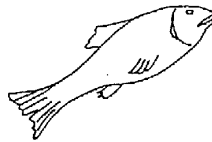
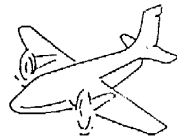
- The six pictures have to be memorized.
- Showing duration : 30 secondes.
- To inform the patient, he has to find in 5 minutes.

Maximum Score = 5

Score:



9550082



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MEMORY TEST
(According to Signoret)

RECOGNITION

Whatever the prior performance, the patient is invited to recognise the 6 pictures among the 24 represented pictures; there is a good picture by row; you have to inform the patient and to get him proceeded row by row.

Maximum Score = 6

EVOCATION + RECOGNITION

Maximum Score = 5 + 6

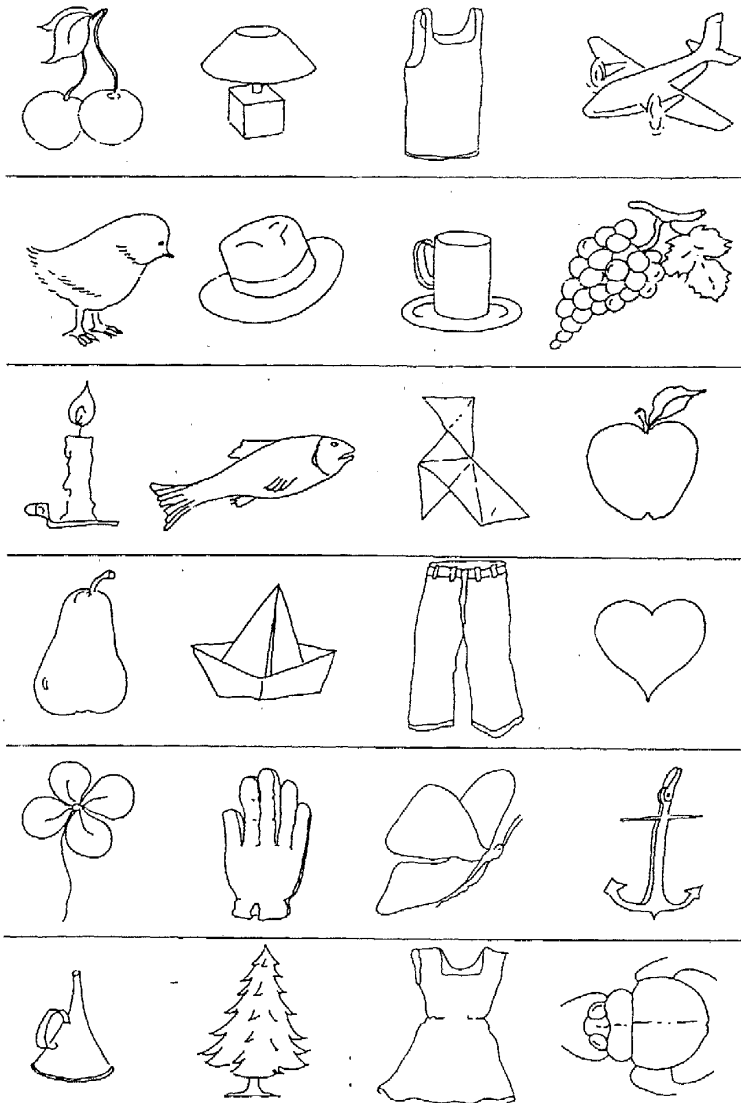
Score < 9 = memory disorder



9550082

RECOGNITION

Can you show me which pictures I saw you, at the beginning of the test.



Score:

643

9550082

ATTENTION / VIGILANCE TEST
(According to Mesulam)

To cross out the A in 2 minutes.

Quotation: A crossed out = +1
Other letter crossed out = -1

Maximum Score = 30

Score < 20 = Attention/Vigilance Disorders

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ATTENTION / VIGILANCE TEST

Let cross out the A; you have got 2 minutes.

E A P W B V A Q H R Y A K O G M A
Z R U A T I L S C X E P W B A Q V
O G A V K Y D U A A B Z T F J A L
L P K R A J E I O Z H V X A Q F W
S A F M Z V A K L E U A R I H P A
R E W C A H P Y Q M J S D A Z V K
I Z X A O B L F T G P Y C W A E R
A J P S R K I A B N A F X U M Q D
Q D C M H W G E V R S B I L Z T Y
A U T I G F S A J O A D P H N R M
W H R A L T B M D V I G O S A K U
P Y N K A S W L U C Q E H A F B J

645

Score:

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COMPOUND: REBOXETINE

PROTOCOL No. : 20124/015

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PHASE : III

TITLE : Multicenter, multinational double-blind study of the activity and tolerability of reboxetine vs imipramine and placebo in patients suffering from Major Depressive Episodes.

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This protocol contains strictly confidential information which is not to be communicated or published unless previously authorized by Farmitalia Carlo Erba R&D.

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TABLE OF CONTENTS

1.0	PROTOCOL SUMMARY	Page	1
2.0	INTRODUCTION	"	1
3.0	RATIONALE	"	4
4.0	OBJECTIVES	"	5
5.0	DESIGN	"	5
5.1	Description	"	5
5.2	Number of subjects proposed	"	5
5.3	Logistics	"	5
6.0	STUDY POPULATION	"	5
6.1	Source of Subjects	"	5
6.2	Inclusion Criteria	"	5
6.3	Exclusion Criteria	"	6
6.4	Identification of subjects	"	7
7.0	RANDOMIZATION AND REGISTRATION PROCEDURES	"	7
8.0	EXPERIMENTAL TREATMENTS	"	7
8.1	Test preparation	"	7
8.2	Labelling	"	8
8.3	Packaging	"	8
8.4	Drug supplies storage	"	8
8.5	Dispensing, use and disposition of test drugs during and at the end of the study	"	8
9.0	STUDY CONDUCT	"	9
9.1	Pre-treatment period	"	9
9.2	Treatment period	"	9
9.2.1	Dose/route of administration/ treatment schedule	"	9
9.2.2	Duration of treatment	"	9
9.2.3	Indications for early termination of test therapy	"	9
9.2.4	Dropouts/Replacement of subjects	"	10
9.2.5	Concomitant therapy	"	10
9.2.6	Indications for opening the code	"	10
9.3	Follow-up	"	11
9.4	Study timetable	"	11
10.0	EFFICACY ASSESSMENTS	"	11
10.1	Variables to be measured for efficacy assessment	"	11

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10.2	Efficacy definition	"	12
10.3	Cognitive function evaluability	"	12
10.4	Criteria for subject evaluability	"	12
11.0	SAFETY ASSESSMENT	"	12
11.1	Variables to be measured for safety assessment	"	12
11.2	Criteria for subject evaluability	"	13
12.0	ADVERSE EVENTS	"	13
13.0	EVALUATION SCHEDULE	"	14
14.0	STATISTICAL CONSIDERATIONS	"	14
14.1	Sample size	"	14
14.2	Statistical analysis	"	15
15.0	ETHICAL ASPECTS	"	16
15.1	Ethical committee	"	17
15.2	Informed consent	"	17
16.0	PROTOCOL AMENDMENTS	"	17
17.0	STUDY MONITORING	"	17
18.0	DRUG SUPPLY AND DRUG INVENTORY	"	18
19.0	ADMINISTRATIVE ASPECTS	"	18
19.1	Insurance policy	"	18
19.2	Curriculum vitae	"	18
19.3	Data collection in the Case Record Form	"	18
19.4	Use and publications of the data obtained from the study	"	19
20.0	STUDY REPORT	"	19
20.1	Clinical Study Final Report	"	19
20.2	Use and publication of the study result	"	19
21.0	END OF THE STUDY	"	19
22.0	STUDY COORDINATION	"	20
23.0	REFERENCES	"	20
24.0	SIGNATURES	"	21
	List of enclosures	"	22
	Table 1. Evaluation schedule	"	23

1.0 PROTOCOL SUMMARY

The study, aimed at the evaluation of the efficacy and tolerability of reboxetine in comparison with imipramine and placebo in patients suffering from Major Depressive Episodes, will be carried out on a multinational basis, according to a double-blind parallel group design, in 330 patients. After an initial washout period of 1-2 weeks, patients will receive either reboxetine or imipramine or placebo, administered according to a fixed-flexible dose regimen, for 6 weeks. Efficacy (Clinical Global Impression, Hamilton Depression Rating Scale, Montgomery-Asberg Depression Rating Scale, Patient Global Impression), and tolerability (newly observed signs and symptoms, lab tests and ECG) will be assessed every 1-2 weeks. At the end of the 6-week treatment period a long-term follow-up may be undertaken.

2.0 INTRODUCTION

Reboxetine (FCE 20124 or RS, RS 2-[α -(2-ethoxy-phenoxy) benzyl] morpholine methanesulphonate) is a chemically new compound highly potent in pharmacological and biochemical tests predictive of antidepressant effectiveness: reserpine antagonism, norepinephrine reuptake inhibition, REM sleep latency increase. In addition reboxetine has been found to be able to prevent clonidine effects in rodents after single oral administration, in contrast with what observed following tricyclic monoamine uptake inhibitors, which were found to be active only upon repeated doses: these results indicate that the compound is able to decrease the sensitivity of α_2 noradrenergic receptors, one of the biochemical correlates of chronic antidepressant treatment, after single oral dose: therefore it may be expected to exert antidepressant effectiveness of faster onset with respect to available antidepressants in patients (1).

In phase I studies (2, 3) single doses of 0.5 - 5 mg of compound, were administered orally to healthy volunteers. After 5 mg orthostatic hypotension, accompanied by tachycardia and by subjective symptomatology consistent with the disturbed circulatory regulation was observed.

In these studies single doses of 1 & 3 mg of the compound showed dose-dependent CNS effects with EEG modifications (decreased power of theta and fast-beta

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waves in the fronto-central derivative), performance improvement (peg-board test) and growth hormone increase, the latter reportedly sensitive to hypothalamic noradrenergic stimulation by norepinephrine reuptake inhibitors.

The comparison with the positive control, imipramine 75 mg, associated to similar EEG modifications in the fronto-central derivative, to modifications indicative of sedative activity in the occipito-temporal derivative and to deterioration of the Pauli performance test, in the absence of growth hormone modifications, indicate that reboxetine does not possess the marked sedative activity of imipramine, but rather psychostimulating properties. After all treatment standing heart rate increase and salivation decrease was apparent. No other modifications of tolerability parameters were observed.

The pharmacokinetics of the compound were evaluated in the above mentioned studies as well as after administration of 2 mg ¹⁴C-FCE 20124 to 3 healthy volunteers (4). Most of the radioactivity circulating in plasma (73% in terms of AUC) was accounted for by unchanged reboxetine; the average peak levels were observed at 2 h, with remarkably stable levels 1-6 hours after administration; its plasma half-life was estimated as 13.2 h, slightly lower than that of total radioactivity.

In addition the autonomic effects of the compound have been evaluated in a study carried out in 16 healthy volunteers according to a double-blind, latin square experimental design. Single doses of reboxetine 1, 2 & 4 mg, desipramine 25, 50 and 100 mg and placebo were administered at weekly intervals. Both reboxetine and desipramine were found to be similarly active in reducing salivation and antagonizing carbachol-evoked sweating, activities consistent with anticholinergic properties, and in increasing heart rate (consistent with muscarinic receptor blockade and/or noradrenergic stimulation); reboxetine, but not desipramine, was found to increase resting pupil diameter (consistent with muscarinic receptor blockade and/or α -stimulation) and to antagonize light evoked-miosis (consistent with anticholinergic activity).

Neither reboxetine nor desipramine were found to modify phenylephrine evoked sweating (no evidence of α -adrenoceptor blockade); following reboxetine a

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reduction of phenylephrine-evoked mydriasis was apparent, possibly due to a "ceiling effect" (due to the mydriatic effect of reboxetine) rather than α -adrenoceptor blockade. No evidence of noradrenaline-uptake blockade could be observed, since noradrenaline failed to evoke measurable pupillary response.

On the basis of the results of the phase I studies, a 6-center early phase II study was carried out aimed at assessing tolerability and activity of progressively increased doses of reboxetine, administered over a 4-week period to hospitalized patients suffering from Major Depressive Disorders (5).

Ninety-eight patients were admitted to the study to be treated with maximum reboxetine daily doses of 4 mg (29 pts), 6 mg (27 pts), 8 mg (18 pts), 10 mg (12 pts) and 12 mg (12 pts). Treatment was discontinued in 4 patients in the 4 mg group due to deterioration of the clinical picture (with a manic syndrome in one case); in 2 patients of the 6 mg group due to the development of a manic episode; in one patient of the 6 mg group due to a convulsive episode, under associated treatment with levomepromazine. Dosage decrease was almost only present in the 12 mg group where in 5/12 cases, due to hypotension and tachycardia, the daily dose was decreased to 10 mg until completion of the treatment period.

The rating scales applied showed dose related improvement of the clinical picture both as average changes vs basal conditions as well as frequencies of relevant modifications (defined as 50% decrease of HAMD) up to the 10 mg/day dose, whereas slight deterioration, concomitant to the intolerance signs/symptoms, was observed in the highest dose group.

The compound was well tolerated when administered at doses up to 10 mg/day, as shown by newly observed signs and symptoms, mainly of mild to moderate severity and transient, and by vital signs and lab tests assessments, ECG included.

A double blind parallel group study was subsequently carried out in 10 centers (Hungary, Italy, France and Latin America) in 258 patients hospitalized due to a Major Depressive Episode. The experimental treatment had to be administered for 4 weeks, with maximum doses of 8 mg reboxetine (RBX) or 200 mg desipramine (DMI). The experimental treatment was discontinued in 26 patients (10%): in 18 cases (5, 6 e 7 of the RBX, DMI

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and P group respectively) for inefficacy; in 3 cases for adverse events (2 of the RBX group due to deterioration of ventricular extrasystoles present before study start and hypertensive episodes respectively and 1 of the placebo group due to a cutaneous rash); in 5 cases (2, 1 and 2 in the RBX, DMI and P group respectively) for reasons unrelated to the experimental treatment.

Of the 80, 82 and 81 cases evaluable for efficacy in the RBX, DMI and P group (after exclusion of protocol violations, mainly related to associated treatments) 63%, 46% and 36% respectively showed a decrease >50% of the HAMD total score at the end of treatment; in 31%, 22% and 21% of these patients respectively the decrease was present within the 14th day of treatment. As to within-center results, the highest frequency of response was observed in the RBX group in all but 3 of the participating centers. After 2 and 4 weeks of treatment an average decrease of 23% and 34% of the HAMD was present in the P group; the corresponding figures were 34% and 49% in the DMI group and 39% e 57% in the RBX group.

As to signs/symptoms, more frequent in the RBX group were headache, complained of by 33% of the patients (20% and 21% in the DMI e P group respectively), and urinary hesitancy/retention, present in 12% vs 4% vs 1% of the cases. RBX vs DMI vs P. More

frequent in the DMI group were dry mouth (45% vs 26% vs 21%, DMI vs RBX vs P), sweating (28% vs 18% vs 22%), blurred vision (17% vs 4% in both RBX and P groups). Cardiovascular signs/symptoms were relatively rare, and appeared with slightly higher frequency in the DMI group: hypotension 13%, vs 6% in the RBX and 8% in the P group and tachycardia 19% vs 12% and 8% in the RBX and P group respectively.

3.0 RATIONALE

Phase II results obtained in controlled conditions in patients suffering from Major Depressive Disorders indicate that reboxetine is an effective antidepressant agent, with a favourable therapeutic index with respect to desipramine. Consistent information from further placebo-controlled studies is needed in order to properly document the activity and tolerability of the compound. In addition comparative evidence vs another tricyclic antidepressant is expected to allow a proper appraisal of the usefulness of the new molecule.

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4.0 OBJECTIVES

To assess activity and tolerability of reboxetine in comparison with placebo and imipramine in patients suffering from Major Depressive Episodes.

5.0 DESIGN

5.1 Description

This phase III study will be carried out according to a double blind parallel group design, controlled vs imipramine and placebo, with random allocation of patients to one of the three treatments. The study will be organized on a multicentre, multinational basis.

5.2 Number of subjects proposed

Each center will recruit 24-42 patients, within a period of 12 months, for a total of 300 patients overall.

5.3 Logistics

The centers participating in the study are listed in enclosure 1.

6.0 STUDY POPULATION

6.1 Source of subjects

Adult patients selected from the population under in-patient care or attending out-patient or day-hospital clinics of the participating centers will be studied. These latter can be hospitalised for the study.

6.2 Inclusion criteria

- Patients affected by acute episodes of Major Depressive Disorders (DSM III R) (enclosure 2) not accompanied by psychotic features, with presence of illness for at least one month and not more than four.
- Patients of either sex, of any race, aged 18 to 65 years.
- A total score of 22 or above in the first 17 items of the 21-HAMD.

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- Patient's consent: informed written consent will be obtained - see 15.2 (proposed form: enclosure 3).

6.3 Exclusion criteria

- Dysthymia, Cyclothymia.
- History of Major Depressive Disorders associated with Endocrine Disorders: hypo and hyper-thyroidism tested by TSH and T4 at admission and defined as at least 10% abnormal values of the laboratory norms; adrenal insufficiency, etc.
- Pregnancy (tested by pregnancy test at the end of the wash-out period).
- Refusal of the use of efficient contraceptive methods by female patients in child bearing age during the study period.
- Past history of any drug hypersensitivity.
- Participation in any clinical study with an investigational compound in the 4 weeks preceding the study.
- Evidence of Substance Use Disorder (DSM-III-R) within past 6 months or currently.
- Chronic respiratory insufficiency in the physical examination and X-ray.
- Progressive illness or systematic disease of the digestive system, liver, or kidney or other conditions known to interfere with the absorption, distribution, metabolism and excretion of drugs.
- History of seizures or brain injury; current evidence of clinically important hematopoietic or cardiovascular diseases. Current evidence of urinary retention, or glaucoma.
- Symptoms of any other important clinical illness in the 4 weeks preceding the study.
- Clinically relevant abnormal findings in the physical examination, laboratory tests and ECG at admission.
- ECT in the previous 3 months.

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- MMS (Mini Mental State) < 22 (enclosure 4).
- Risk of suicide.
- The use of any psychotropic agent which cannot be removed during the entire experimental study.
- Clinical improvement at the end of the washout period (decrease of the HAMD of at least 1 point).

6.4 Identification of subjects

Patients will be identified by their initials and by the number in the trial.

7.0 RANDOMIZATION PROCEDURES

A randomization list balanced within center will be prepared for patient allocation to one of the 3 possible treatments (reboxetine, imipramine or placebo). On this basis the experimental treatments will be prepared and labelled with the corresponding patient number. Patient allocation to treatment will be done at the end of the pre-treatment period by the main Investigator on the basis of the patient's temporal entry into the study.

8.0 EXPERIMENTAL TREATMENTS

8.1 Test preparation

Indistinguishable capsules containing reboxetine 4 mg (2 tabl of 2mg, batch no.....) or 6 mg (3 tabl of 2mg, batch no..) or imipramine 50 mg (2 tabl of 25mg, batch no.....) or 100mg (4 tabl of 25mg, batch no.....) or excipients only (placebo, batch no...) will be used. The experimental treatments will be administered according to fixed-flexible dose schedules as indicated under Study Conduct. Test preparations will consist of:

	morning	evening
-reboxetine	1 cps 4 mg	1 cps 4 mg
-reboxetine DOSE 2 (last 3 weeks)	as above	1 cps 6 mg
-imipramine day 1-3	1 cps 50 mg	1 cps 50 mg
day 4-42	1 cps 50 mg	1 cps 100 mg
-imipramine DOSE 2 (last 3 weeks)	1 cps 100 mg	1 cps 100 mg
-placebo	1 cps	1 cps
-placebo DOSE 2 (last 3 weeks)	as above	as above

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8.2 Labelling

The experimental treatment will be labelled by using the labels in enclosure 5. Double labels will be used.

8.3 Packaging

For each patient 6 cartons labelled with the patient number and the indication "week 1" to "week 6" will be prepared. Each carton will contain the medication necessary for 1 week plus 2 cps for possible losses, prepared according to the b.i.d. regimen with 1 cps for the "morning" and 1 cps for the "evening" dose. In addition for each patient 3 cartons labelled with the patient number and the indication "week 4-dose 2", "week 5-dose 2" and "week 6-dose 2" will be provided, for the possible dosage increase during the last 3 weeks of treatment (see Study Conduct).

8.4 Drug supplies storage

Drug supplies will be stored at room temperature. All drug supplies will be handled under the direct responsibility of the Investigator and held by the Hospital Pharmacy. The study Monitor will check drug storage conditions during site visits.

The Investigator will be also responsible for drug accountability and will keep a record of the test compounds received from the Sponsor as well as of the dispensed drug.

8.5 Dispensing, use and disposition of test drugs during and at the end of the study

Medication will be dispensed to the patient on the occasion of each visit; the Investigator will detach the upper label from each of the weekly cartons he is dispensing to the patient and will attach them in the appropriate space in the Case Record Form. On the same occasion cartons of the possible previous supply will be returned by the patient.

Used cartons will be returned to the study Monitor during site visits.

All unused medication has to be returned to Farmitalia Carlo Erba at the end of the study.

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9.0 STUDY CONDUCT

9.1 Pre-treatment period

Patients will be checked for eligibility according to the inclusion and exclusion criteria. A washout period of 4-7 days (14 days in case of MAOI administration and 3 - 4 weeks in the case of previous fluoxetine treatment) will then be undertaken, during which only chloral hydrate (0.5 - 1g) as sleep inducer on p.r.n. basis will be allowed. Informed consent will be obtained from each patient.

Eligible patients will be then randomized to one of the three treatment groups and will undergo baseline assessments.

Information on patients screened for the study and found not to be eligible will be collected in the appropriate form (screening form, enclosure 6).

9.2 Treatment period

9.2.1 Dose/route of administration/treatment schedule

Treatments will be administered under close monitoring (hospital or day hospital for the first two weeks at least) to reduce suicidal risk to a minimum.

Patients will receive 1 capsule b.i.d. from day 1 to day 42. In case of inefficacy or unsatisfactory response (slight worsening or no change or minimal improvement at the CGI, see assessments), the dose will be increased to "dose 2" (see 8.0 Experimental Treatments) from day 22 to day 42, i.e. up to the end of treatment. In case of intolerance the dose will be reduced to the previously well tolerated lower dosage level.

The treatments will be administered in the morning and in the evening, at least 2 hours before or after meals.

9.2.2 Duration of treatment

The experimental treatment will be administered for 6 weeks.

9.2.3 Indications for early termination of test therapy

Termination of test therapy prior to completion of the 6 weeks treatment period may be considered under the following circumstances:

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- Patient's request
- Switch to mania
- Unacceptable toxicity: this is defined as the occurrence of serious (see Adverse Events) adverse events (see 12.0)
- Lack of efficacy: this will apply to patients who will show unacceptable deterioration after 2 weeks of treatment (worsening in CGI)

In case of treatment discontinuation the complete final battery of assessments will be carried out.

9.2.4 Dropouts/replacement of subjects

Patients who drop out of the study for any reason will not be substituted.

For those patients who have been selected for the study who drop out at any time, even if it is before entrance to the treatment period, documentation will be provided.

9.2.5 Concomitant therapy

No concomitant medications other than hypnotic on p.r.n. basis are allowed at entry into the study. Concomitant medication should be avoided throughout the study. In case the events arising during the course of the study nonpsychotropic medications which are considered necessary for the patient's welfare may be administered and will not be considered violation to the protocol. The drugs, dosage and frequency of administration will be recorded. Chloral hydrate(0.5-1g/night) as sleep inducer on p.r.n. basis at bed-time is allowed.

9.2.6 Indications for opening the code

The Investigator will be given individual sealed envelopes containing the information on patient's treatment. These latter may be opened only in case of emergency necessitating treatment identification; the Investigator will immediately (within 24 hours) inform the study Monitor at FICE Subsidiaries and will report full description of reasons for opening the code in the CRF (Adverse Event Form).

The sealed individual codes will be returned to Farmitalia Carlo Erba at the end of the study.

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9.3 Follow-up

A follow-up visit will be carried out for each patient one month after treatment discontinuation, in order to monitor possible withdrawal reactions and collect information on interval events.

Patients willing to continue receiving the experimental treatment after completion of the 6 weeks treatment period will be maintained under the same medication in blind conditions until completion of the last patient of the center. Monthly visits will be carried out for efficacy and safety assessment and drug dispensing. The medications will be prepared as described for the initial double-blind treatment period, but in monthly units.

Afterwards, patients will be followed-up in open conditions. Reboxetine tablets will be provided by Farmitalia Carlo Erba while, for those patients who were receiving imipramine, Tofranil will be prescribed.

9.4 Study timetable

Foreseen start date: March 91
Duration of accrual: 12 months
Foreseen end date (date of the last visit of the last patient, excluding follow up): April - May 92

10.0 EFFICACY ASSESSMENTS

10.1 Variables to be measured for efficacy assessment

On days 0, 7, 14, 21, 28, 35, 42 :

- Hamilton Depression Rating Scale (21 items HAMD, enclosure 7); as above plus at screening for entry and monthly during the follow-up period.

- Clinical Global Impression (Enclosure 8), as above plus monthly during the follow-up period.

- Montgomery-Asberg Depression Rating Scale (Enclosure 9)

- Patient Global Impression (Enclosure 10)- excluding day 0

- Relational rating scales (Enclosure 11)

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The latter is adopted in order to explore relational aspects of the Depressive Disorders; Investigators are expected to propose 1-2 additional items of relevance for each patient in their opinion. Consistency of suggestions will be evaluated and on this basis an International Scale developed.

All psychiatric evaluations and ratings will be carried out by the same observer for a given patient, preferably in the same setting and at the same time of the day.

10.2 Efficacy definition

Decreases of at least 50% in the total HAMD score vs day 0 will be considered index of response whereas total HAMD score of 10 or less will be considered index of remission.

10.3 Cognitive function evaluation

Cognitive function will be evaluated on the day 0, day 14, and at the end of the study according to the model tests described in Attachment C.

10.4 Criteria for subject evaluability

Every randomized patient (see 7.0) will be included in the analysis.

11.0 SAFETY ASSESSMENT

11.1 Variables to be measured for safety assessment

- Standard medical history: at screening
- Standard clinical examination: full physical examination: at screening
- Blood pressure and pulse will be measured in the lying (after 5 minutes lying) and in the standing position (1 -2 minutes after standing up) in the morning: at screening and at each visit.
- ECG: at screening, day 21, day 42 and every three months during follow-up.
- Chest X-ray: at screening

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- Laboratory: TSH and T4 at screening; full blood count, sodium, potassium, chlorine, BUN, creatinine, glucose, bilirubin, calcium, phosphorus, SGOT, SGPT, gamma GT, alkaline phosphatase, LDH, total proteins, albumin, cholesterol, uric acid, triglycerides, globulins - α_1 , α_2 , β , gamma -, urinalysis: at screening, day 21, day 42 and every three months during follow-up.

- Adverse events: a check-list will be administered at each visit (Enclosure 12).

11.2 Criteria for subject evaluability

Every patient who has received at least one dose of the experimental treatment will be included in the safety evaluation.

12.0 ADVERSE EVENTS

Patients will be notified of possible adverse events they could experience and instructed to immediately report them to the Investigator.

Any newly observed sign or symptom, noticed by the Investigator or complained of by the patient, including clinically relevant lab abnormalities, will be recorded in the appropriate section of the CRF, regardless of presumed relationship to study medication.

For each event, the following information will be entered in the CRF: description, onset date, disappearance date, severity (1 = mild, awareness of sign or symptom, but easily tolerated; 2 = moderate, discomfort enough to cause interference with usual activity; 3 = severe, incapacitating with inability to work or do usual activity; 4 = unknown), drug cause-effect relationship (according to Karch and Lasagna modified criteria; see enclosure 13), outcome, dechallenge (what happened to the adverse event when the drug was stopped or the dose decreased?) rechallenge (what happened when the drug was restarted after the adverse event had disappeared?). The Investigator will also note if the double-blind code has been opened, the action taken regarding the test drug (none, discontinued, dosage reduced) and any treatment applied because of the adverse reactions.

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All serious* ("any experience that is (potentially) fatal or life-threatening, disabling, incapacitating, requires inpatient hospitalization, or causes a congenital anomaly or cancer or is due to overdose") and/or unexpected* ("any adverse experience that is not identified in nature, severity or frequency in the current investigator's brochure for the study") adverse events must be immediately (within 24 hours) reported by telephone to FICE Subsidiaries Monitors (see Section 17.0) and the Adverse Event Report Form (enclosure 14) must be filled in immediately. FICE will notify the Regulatory Authority in accordance with statutory requirements. The same applies to all patients who die, irrespective of whether the event was judged as related to treatment, during the course of the study or within 30 days of completion of treatment.

In case of death, if an autopsy is performed, a copy of the pathological report should be sent to the FICE subsidiary monitor.

13.0 EVALUATION SCHEDULE

Is reported in table 1.

14.0 STATISTICAL CONSIDERATIONS

14.1 Sample size

The main evaluation of treatment effectiveness will be based on the comparison with respect to placebo of the total score of the HAMD. The study shall be sized to evidentiate the difference between baseline and the last postbaseline score for each patient regardless of length of time in the study. Thus, this analysis, requiring at least one visit after baseline, takes into account differential dropout rates among treatment groups.

Either imipramine and reboxetine will be compared to placebo. The first comparison is set up in order to establish the sensitivity of the trial, while the second one will allow the evaluation of the new compound (reboxetine).

* Code of Federal Regulation, Vol 21 Part 312. Revised as of April 1, 1987, pg. 75.

* J.L.Bem et al.: Review of yellow cards (1986): report to the Committee on the Safety of Medicines. Br.J. Clin. Pharmac. (1988), 26, 679-689.

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Therefore the following hypothesis systems set up:

$$H_0: \delta_t \geq \delta_p \quad \text{i.e.} \quad \delta_t - \delta_p \geq 0$$

$$H_a: \delta_t < \delta_p \quad \delta_t - \delta_p < 0$$

where δ_t and δ_p represent respectively the true mean of the distribution of the difference from baseline of total score of the HAMD for reboxetine (or imipramine) and placebo.

In order to take into account the multiplicity of the comparisons, the criterion of Bonferroni is applied. Consequently the α level for the simultaneous inference is fixed at 0.025 for each comparison (overall α level = 0.05) (this is equivalent to the Dunnett procedure which would lead to an α level of 0.024 for each comparison).

From the phase II trial and from the literature (6) it seems reasonable to assume that treatment groups will show a variability (expressed as standard deviation) of 9 points. Considering of clinical relevance a difference between reboxetine, or imipramine, and placebo of at least 4 points, 80 patients per group are necessary in order to provide a power ≥ 0.80 if the alternative hypothesis is true, with the α level fixed at 0.025, for each of the two tests. Taking into account the possibility of dropouts before the first postbaseline visit and nonevaluable patients according to protocol criteria, 100 patients per group should be recruited.

14.2 Statistical analysis

The main analysis of treatment effectiveness will be carried out on the variable 'total score of HAMD' considering the difference between baseline and the last postbaseline score for each patient regardless of length of time in study. Both reboxetine and imipramine will be compared to placebo. Consistently with the method used for the sample size calculation a multiple t test procedure will be adopted to test the null hypothesis. Analysis of variance will produce the appropriate estimate of residual variability.

Evident unbalances among baseline values in the three groups will be taken into account by means of analysis of covariance. As secondary aim reboxetine will be compared to imipramine in respect to HAMD total score considering the difference between baseline and the last postbaseline score for each patient. In this case a two tail test will be applied. Confidence interval

9550082

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of the difference between treatment mean decrements vs baseline will also be computed.

In order to have a more complete picture of reboxetine effectiveness results obtained from the other administered scales (Montgomery-Asberg, CGI, PGI) as well as response/remission rates will be considered. Response/remission rate is defined as the proportion of randomized patients experiencing response/remission (see 10.2) at a fixed time.

All the efficacy variables will be analysed taking into account both the values obtained at the last postbaseline visit and values obtained at each week. Explorative comparisons among the three groups will be performed.

Time course of the score of the administered rating scales will be described for all the three groups. Time trend analysis will be performed on patients completing the six weeks treatment period. If judged to be informative, weekly analysis, including only those patients remaining in the study at a particular week, will be carried out.

Dropouts will be classified by reasons for study termination and proportions of patients dropped out compared among groups.

Frequencies of patients showing maximum decrease ≥ 20 mmHg in the standing systolic blood pressure will be compared among groups.

Adverse events will be presented by patient-by-patient listing and tabulated by treatment both on a patient basis and on an event basis. If clinically significant differences arise, they will be submitted to non parametric test of the differences among treatment groups.

Descriptive statistics (mean, median, etc.) for laboratory data will be provided as well as frequency of abnormal values, with respect to normal range, after treatment in each group.

15.0 **ETHICAL ASPECTS**

The study will be carried out according to the Helsinki Declaration (Venice revision, Enclosure 15)

9550082

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15.1 Ethical Committee

This study will not be undertaken until approval is obtained from the Ethical Committee Institutional Review Board (IRB) of the participating centres. It is responsibility of the Investigator to submit the study protocol with its attachments to the Ethical Committee.

The written approval of the Ethical Committee or IRB will report the name and profession of all its members and a copy of it will be sent to the Sponsor before the study begins.

The Investigator is committed, in compliance with local requirements, to inform the Ethical Committee of any emergent problems, serious adverse reactions or protocol amendments.

15.2 Informed consent

Before entering the study each patient will be receive an explanation of the nature, duration, and purpose of the study and the action of the compounds in such a manner that the patient is aware of the potential risks, inconveniences or adverse effects that may occur and can express his/her informed consent to participate. The consent form (enclosure 1) will be signed by the patient or by the Investigator. In the latter case, the signature of a witness will testify that full information was given to the patient.

16.0 PROTOCOL AMENDMENTS

After the protocol has been signed, no changes will be made without the agreement of both the Investigator, the Steering Committee and the Sponsor. Any change will be recorded on a written agreement which will be signed and dated by both parties and attached to the original protocol. No protocol change will be implemented without Regulatory approval, where required.

17.0 STUDY MONITORING

The monitors of the study are listed in enclosure 16.

A pre-study visit will be made by the monitor to the Investigator in order to discuss problems, if any, and

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the obligations of both the Sponsor and the Investigator. During the trial monitoring visits will be paid to the site by the study monitor every four weeks. During the visits the monitor will assess the progress of the study, review the compliance with the study protocol, discuss any problem, check the CRFs for legibility, accuracy and completeness, validate CRFs content against source documents, assess the status of drug storage dispensing and retrieval.

Operating procedures for training on assessment instruments, study monitoring and coordination are described in attachment A.

18.0 DRUG SUPPLY AND INVENTORY

Test preparation will be supplied by Farmitalia Carlo Erba in the form described in 8.1. Records will be kept by the Investigator as to the disposition of study drug for each patient. A disposition form accounting for all study supplies will be signed by the Investigator (enclosure 17).

19.0 ADMINISTRATIVE ASPECTS

19.1 Insurance policy (enclosure 18)

Farmitalia Carlo Erba Company declares to have a group insurance cover (policy NO. 4W8102 - Italia Assicurazioni) which provides indemnity to the Investigator, to the co-Investigators and to the subjects participating in the trial.

19.2 Curriculum vitae

The Investigator will provide the Sponsor with signed copies of his/her and his/her co-Investigators CVs.

19.3 Data collection in the Case Record Form

All study data will be recorded in the CRF supplied by the Sponsor (Attachment B). A black ink ball point pen should be used for entering the data to ensure the good quality of the reproduced CRFs copies.

Only the Principal Investigator and the duly authorized co-Investigators can make entries in the CRF.

In case of errors corrections must be made by crossing out the incorrect entry (that must remain legible) and entering the correction followed by the Investigator's initials and the date of the correction.

9550082

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On the occasion of the monitoring visits the monitor will take away the original and one copy of each page, while the Investigator will retain a copy for his files, together with the drug disposition records, for ten years after the discontinuation of the investigation.

19.4 Use and publication of the data obtained from the study

All unpublished documentation including the protocol, the CRF and the Investigator's Brochure, given to the Investigator is confidential. These documents cannot be disclosed to a third party without the written consent of FICE R&D. The submission of these documents to the Ethical Committee is expressly permitted.

The Investigator agrees that FICE R&D maintains the right to utilize the results of this study, in their original form and/or in a global report, for submission to the governmental and regulatory authorities of any country.

20.0 STUDY REPORT

20.1 Clinical Study Final Report

The final Medical Study Report will be written by the Product Leader and will be submitted to the Investigator for approval and signature.

20.2 Use and publication of Study Results

The Investigators, whilst free to use the data resulting from this study, are asked to discuss any paper with Farmitalia Carlo Erba prior to publication; to this purpose copy of manuscript/abstract as to be available for FICE R&D Approval Procedure 30 days prior to publication.

The results of the study may be submitted for a common publication, agreed upon between the Investigator and FICE R&D.

21.0 END OF THE STUDY

The Investigator or FICE R&D could terminate this study at any time for well documented reasons. In this event the other party will be immediately notified.

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22.0 STUDY COORDINATION

A Steering Committee in charge of the coordination of the study will be formed, as described in Attachment A.

23.0 REFERENCES

1. Reboxetine Investigator Brochure, FICE, CNS Line, June 1988
2. /602i - Herrmann W.M. et al. (AFB - Berlin)
Safety and tolerance of reboxetine in healthy male volunteers - A single rising dose tolerance study.
June 15 1984.
3. /603i - Herrmann W.M. (AFB - Berlin)
Reboxetine - Quantitative pharmaco EEG and pharmaco-psychological study.
January 1985.
4. /604i - Dubini A. et al.
Disposition and fate of ¹⁴C-reboxetine administered orally to healthy volunteers.
March 1985.
5. /701 - A. Dubini, T. Ban
Reboxetine: Open Dose Range Finding study in patients hospitalized for major depressive disorders February 89
6. Stark P., Hardison D.
J. Clin. Psychiatry, 46:53-58, 1985

668

9550082

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24.0 **SIGNATURES**

Signatures of the:

Investigator _____

Study Monitor _____

Product Leader _____

Line Medical Head _____

Biostatisticians _____

669

9550082

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CNS LINE

LIST OF ENCLOSURES

- 1) LIST OF CENTERS
- 2) DSM-III-R CRITERIA
- 3) CONSENT FORM
- 4) MMS: MINI MENTAL STATE
- 5) EXPERIMENTAL TREATMENT LABELLING
- 6) SCREENING FORM
- 7) HAMD: HAMILTON DEPRESSION RATING SCALE
- 8) CGI: CLINICAL GLOBAL IMPRESSION
- 9) MADRS: MONTGOMERY ASBERG DEPRESSION RATING SCALE
- 10) PATIENT GLOBAL IMPRESSION
- 11) RDRS: RELATIONAL RATING SCALE
- 12) ADVERSE EVENTS: CHECK LIST
- 13) KARCH AND LASAGNA MODIFIED CRITERIA
- 14) ADVERSE EVENTS REPORT
- 15) DECLARATION OF HELSINKI
- 16) LIST OF MONITORS
- 17) DRUG ACCOUNTABILITY FORM
- 18) INSURANCE POLICY

ATTACHMENT A

PROTOCOL 20124/015: OPERATING PROCEDURES FOR TRAINING ON
ASSESSMENT INSTRUMENTS, STUDY MONITORING AND COORDINATION

ATTACHMENT B

CASE RECORD FORM

ATTACHMENT C

COGNITIVE FUNCTION EVALUATION
Appendix 1 : Manual for COGNITIVE EVALUATION
Appendix 2 : Manual for MEMORY ASSESSMENT

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TABLE 1 **EVALUATION SCHEDULE**

DAY	SCREEN	0	4	7	14	21	28	35	42
REX mg		8							
TREATMENT IMI mg		100-150					10		
PLACEBO							200		

DIAGNOSIS : DSM III R	■								
MEDICAL HISTORY	■								
PHYSICAL EXAMINATION	■								
MMS	■								
VITAL SIGNS	■	■		■	■	■	■	■	■
ECG	■					■			■
X-RAY	■								
LABORATORY	■					■			■
Z1-ITEM HAMD	■	■		■	■	■	■	■	■
CGI		■		■	■	■	■	■	■
MADRS		■		■	■	■	■	■	■
PATIENT GLOBAL IMPR.				■	■	■	■	■	■
RELATIONAL RATING SCALE		■		■	■	■	■	■	■
COGNITIVE EVALUATION		■			■				■
ADVERSE EVENTS		■		■	■	■	■	■	■

671

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Enclosure 1

LIST OF PARTICIPATING CENTERS

No.	Country	Principal Investigator (Institution, Address)	Number of patients
1.	Australia	Prof. G.D.Burrows Department of Psychiatry University of Melbourne, Austin Hospital, Heidelberg, Vic. 3084 phone: +613/4505111	24
2.	France	Prof. Pellet Hopital Bellevue, Boulevard Pasteur Service de Psychiatrie 42043 Saint Etienne Cedex	24
3.	France	Dr. Chabannes Clinique du Nivolet Service de Psychiatrie, B.P. 126 73011 Chambéry Cedex	24
4.	France	Dr. Haxaire Cabinet Médical, 15 bd Joffre A 54000 Nancy	24
5.	France	Prof. Leger Centre Hospitalier Spécialisé "Esquirol" 15 rue du Docteur-Marcland 87025 Limoges Cedex	24
6.	France	Dr. Cullerre Cabinet Médical 189 rue Colonel Jean Muller 56000 Lorient	24
7.	Germany	Dr. Benkert University of Mainz	24

672

20124/015 Canada

Date: February 26, 1991

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12.1.2 CRF SAMPLE

A complete CRF is filed in the Study Master File.

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**12.1.3 ETHICS COMMITTEES OR INVESTIGATIONAL REVIEW BOARDS:
APPROVALS, LIST OF MEMBERS, PATIENT INFORMATION AND
CONSENT FORMS**

Investigational Review Boards and Ethics Committees approvals were obtained according to local regulations and laws: copy of the approval documents and, in case of Ethics Committees, list of members are filed in the Study Master File.

The proposed consent form is enclosed (Enclosure 3 of Appendix 12.1.1). Copy of forms approved by Ethics Committees and local translations are filed in the Study Master File.

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12.1.4 CLINICAL INVESTIGATORS LIST, SIGNATURES AND CURRICULA VITAE

- Centre 1: Dr R Gupta (principal investigator)
Phillip Health Centre, Woden, Canberra, Australia
- Centre 2/1: Prof J Pellet (principal investigator)
Dr MLJ Pichon (co-investigator)
Hôpital Bellevue, St. Etienne, France
- Centre 2/2: Dr JL Terra (principal investigator)
Dr C Bourdet, Dr S Besançon, Dr JL Salinas (co-investigators)
Centre Hospitalier Spécialisé, Le Vinatier - Secteur G10, Lyon, France
- Centre 2/3: Dr H Scharbach (principal investigator)
Dr J Guilloux (co-investigator)
CHU Service Médico-Psycholog., Nantes, France
- Centre 2/4: Dr G Leibovici (principal investigator)
Avenue de la Serane, Marseille, France,
- Centre 2/5: Dr RA Castiglioni (principal investigator)
Hôpital Sainte Marguerite, Service de Psychiatrie, Marseille, France
- Centre 2/6: Dr Z Hourri (principal investigator)
Clinique Psychiatrique du Parc, Nantes, France
- Centre 3/1: Dr M Costes (principal investigator)
Dr L Gujadhur (co-investigator)
Centre Hospitalier Spécialisé, Saint Egrève, France
- Centre 3/2: Dr JP Chabannes (principal investigator)
Dr P Sechier (co-investigator)
Centre Hospitalier Spécialisé de Bassens, Chambéry, France

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- Centre 3/3: Prof M Goudehand (principal investigator)
Dr P Thomas (co-investigator)
Unité de Soins Normalisés, Lille, France
- Centre 3/4: Prof G Briole (principal investigator)
Dr A Payen, Dr D Vallet, Dr P Clervoy, Dr A Sumer-Churlaud (co-investigators)
Hôpital d'Instruction des Armées du Val-de-Grace, Paris, France
- Centre 4/1: Dr JC Haxaire (principal investigator)
Dr F Nicolas, Dr N Bertoni (co-investigators)
Bd Joffre, Nancy, France
- Centre 4/2: Dr G Campa (principal investigator)
Rue Nestor Cornier, Grenoble, France
- Centre 4/3: Dr C Blanchard (principal investigator)
CH, St Nazaire, France
- Centre 4/4: Dr R Pagot (principal investigator)
Centre Hospitalier Spécialisé, Saint-Ave, France
- Centre 5/1: Prof JM Leger (principal investigator)
Dr JF Therme, Dr S Altuzarra, Dr C Franceschi (co-investigators)
CHU - Service de Psychiatrie, Limoges, France
- Centre 5/2: Dr JM Bouchard (principal investigator)
Dr E Pezé (co-investigator)
Centre Hospitalier Spécialisé Gerard Marchant, Toulouse, France
- Centre 5/3: Dr JF Charbonnier (principal investigator)
Hôpital St Jacques, Clermont-Ferrand, France
- Centre 6/1: Prof S Brion (principal investigator)
Dr A Fallet, Dr J Gailledreau, Dr V Mahe (co-investigators)
Hôpital Richaud, Service de Psychiatrie, Versailles, France

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- Centre 6/2: Dr PYH Cullerre (principal investigator)
Dr Le Brenn (co-investigator)
Rue Colonel Jean Muller, Lorient, France
- Centre 6/3: Dr B Baranowski (principal investigator)
Rue de Nemours, Rennes, France
- Centre 7/1: Dr EU Vorbach (principal investigator)
Psychiatrische Klinik, Elisabethenstift, Darmstadt, Germany
- Centre 7/2: Prof M Hummel (principal investigator)
Dr T Reüster, Dr B Wennhold (co-investigators)
Psychiatrische Univ. Klinik, Marburg/Lahn, Germany
- Centre 7/3: Prof HJ Schierle (principal investigator)
Puisseaux Platz, Rodgau, Germany
- Centre 7/4: Prof T Schmitt (principal investigator)
General Hospital, Waldbrunn-Hintermeilingen, Germany
- Centre 7/5: Prof P Mayr (principal investigator)
Mozartstr, Stockach, Germany
- Centre 7/7: Prof J. Schimek (principal investigator)
Münchener Str., Frankfurt, Germany
- Centre 8: Prof E Aguglia (principal investigator)
Dr G Quarantotto, Dr P Duse (co-investigators)
Dept. of Psychiatry, Università di Trieste, Trieste, Italy
- Centre 8a: Prof E Aguglia (principal investigator)
Dr M Santagati, Dr G Barbagallo, Dr C Caprino Campana (co-investigators)
Associazione Croce al Vallone, Biancavilla CT, Italy

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- Centre 9: Prof E Smeraldi (principal investigator)
Dr P Della Maggiore, Dr L Bellini, Dr V Brancato (co-investigators)
Ospedale S Raffaele - Villa Turro, Milano, Italy
- Centre 11: Prof RG Priest (principal investigator)
Dr J Steinert, Dr RC Gimbrett, Dr MC Roberts (co-investigators)
Academic Dept of Psychiatry, St Mary's Hospital, London, UK
- Centre 12: Prof M Ohayon (principal investigator)
Dr E Stip, Dr JY Roy (co-investigators)
Centre of Research, Louis La Fontaine Hospital, Montreal, Canada
- Centre 13: Prof GD Burrows (principal investigator)
Dr S Gyorki (co-investigator)
Department of Psychiatry, University of Melbourne, Austin Hospital,
Heidelberg, Australia
- Centre 14: Prof JWG Tiller (principal investigator)
Dr V Tuckwell, Dr KP Maguire, Dr ACN Holmes, Dr AM Keogh (co-
investigators)
The Royal Hospital, Melbourne, Australia
- Centre 15: Dr T George (principal investigator)
The Prince Charles Hospital, Chermside, Brisbane, Australia

Investigators' signatures and Curricula Vitae are filed in the Study Master File.

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12.1.5 CERTIFICATES OF ANALYSIS

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CENTRO RICERCHE
VIA GIOVANNI XXIII, 33
20014 NERVIANO
TELEFONO (0331) 587250
TELEGRAMMI FARMITALIA CARLO ERBA NERVIANO
CASELLA POSTALE 7
TELEX 310319 MONTEO PER FARMITALIA NERVIANO

 **FARMITALIA CARLO ERBA**

DATA December 9th, 1992

CERTIFICATE OF ANALYSIS

REBOXETINE 4 mg capsules

Batch SF 1131

Manufacturing date : September, 1990
Expiry date : June, 1993
Appearance : red-brown, hard-gelatin capsule, snap-fit, size No. 0, containing two 2 mg Reboxetine white, round, convex, 6 mm diameter tablets, marked S.F. on one surface (batch No. SF 1105)
Identification : positive
Average weight : mg 202.01
Uniformity of content : within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.2
Assay : mg 3.998 of Reboxetine/capsule
Related substances : 1.04%
Disintegration : 6 minutes
Microbial contamination : total viabl aerobic count < 1000 moulds and yeasts < 100
E. Coli and Salmonellae : absent
Reanalysis date : December 9th, 1992

Note : this certificate replaces the previous one, edited on March 11th, 1992, owing to the extension of the shelf-life

Approved by : V. Busnelli 

GPI. SEDE LEGALE 41 MILANO
CAPITALE SOC. L. 528 /12 197.000 / /
TRIBUNALE MILANO IG. FO. 11 238246
VOL. 6356 - FASC. 46 - CCIAA N. 1171977
COD. FISC. E PART. IVA N. 27608209156

680 GRUPPO ERBAMONT

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Data January 24th, 1994

Vs. Rif.

Ns. Rif.

Tel. Diretto

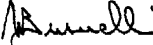
CERTIFICATE OF ANALYSIS No. PC/267

REBOXETINE 4 mg capsules

Batch SF 1264

Manufacturing date : October, 1991
Expiry date : September, 1994
Appearance : red-brown, hard-gelatin capsule, snap-fit, size No. 0, containing two 2 mg Reboxetine white, round, convex, 6 mm diameter tablets, marked S.F. on one surface (batch No. SF 1249)
Identification : positive
Average weight : mg 201.10
Uniformity of content : within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.2
Assay : mg 3.95 of Reboxetine/capsule
Dissolution : 93.9% of the L.A. after 15 minutes
Disintegration : 6 minutes
Microbial contamination : total viable aerobic count < 1000 moulds and yeasts < 100
E. Coli and Salmonellae : absent

Note : this certificate replaces the previous one edited on May 14th, 1992, vis-a-vis the extension of shelf-life

Approved by : V. Busnelli 
681

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Trib. Milano R.S. N. 238246
Vol. 6366 - Fasc. 46

C.C.I.A.A. N. 1171077
Cod. Fisc. e Part. IVA
N. 07608290156

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CENTRO RICERCHE
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TELEFAX 03310679 MONTE PER FARMITALA NERVIANO

 FARMITALIA CARLO ERBA

December 9th, 1992

DATA

CERTIFICATE OF ANALYSIS

REBOXETINE 6 mg capsules

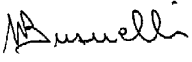
Batch SF 1132

Manufacturing date : September, 1990
Expiry date : June, 1993
Appearance : red-brown, hard-gelatin capsule, snap-fit, size No. 0, containing three 2 mg Reboxetine white, round, convex, 6 mm diameter tablets, marked S.F. on one surface (batch No. SF 1105)
Identification : positive
Average weight : mg 302.97
Uniformity of content : within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.2
Assay : mg 5.993 of Reboxetine/capsule
Related substances : 0.74%
Disintegration : 6 minutes
Microbial contamination : total viabl aerobic count < 1000 moulds and yeasts < 100
E. Coli and Salmonellae : absent
Reanalysis date : December 9th, 1992

Note : this certificate replaces the previous one, edited on March 11th, 1992, owing to the extension of the shelf-life

Approved by

682

: V. Busnelli 

SPR. DEPT. 10044-1/11/1992
CAS. PALE. 10044-1/11/1992
PUBBLICAZIONE 10044-1/11/1992
VOL. 6306 - FASC. 46 - 10044-1/11/1992
CON. 10044-1/11/1992

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VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 6995.1 (CENTRALINO)
TELEGRAMMI ERBACAR MILANO
CASSELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA I-

DATA May 7th, 1992

VS. RIF.

NS. RIF.

TEL DIRETTO

CERTIFICATE OF ANALYSIS

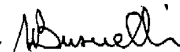
REBOXETINE 6 mg capsules

Batch SF 1291

Manufacturing date : March, 1992
Expiry date : September, 1994
Appearance : red-brown, hard-gelatin capsule, snap-fit, size No. 0, containing three 2 mg Reboxetine white, round, convex, 6 mm diameter tablets, marked S.F. on one surface (batch No. SF 1249)
Identification : positive
Average weight : mg 303.66
Uniformity of content : within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.2
Assay : mg 6.08 of Reboxetine/capsule
Related substances : 0.19%
Disintegration : 6 minutes
Microbial contamination : total viable aerobic counts < 1000 moulds and yeasts < 100
E. Coli and Salmonellae : absent

Approved by

683

: V. Busnelli 

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TRIBUNALE DI MILANO P.5 N. 2392/86
VOL. 6386 - FASC. 16 - C.C.I.A.A. N. 117077
COD. FISC. E PART. IVA N. 07608290156

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VIA CARLO MONSIEU, 23
20159 MILANO

TELEFONO 02 699511 (CENTRALINO)
TELEGRAMMI ERBACAR MILANO
CASSELLA POSTALE 10610
C.C. POSTALE 919205
TELEX 330111 ERBA I

 **FARMITALIA CARLO ERBA**

DATA October 22, 1990

VS. RIF

NS. RIF

TEL. CAPETTO

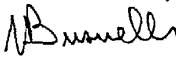
CERTIFICATE OF ANALYSIS

PLACEBO for Reboxetine 4 mg capsules

Batch SF 1133

Manufacturing date	: September 1990
Description	: hard-gelatin capsule, opaque red-brown, size No. 0, containing two white, round, convex, 6 mm diameter placebo tablets for reboxetine 2 mg, marked S.F. on one surface
Average weight	: 203.63 mg
Uniformity of mass	: complies, according to Eur. Ph., 2nd Ed., requirements
Identification	: negative
Disintegration time	: 6 minutes
Microbial contamination	: total viable aerobic count < 1000 moulds and yeasts < 100 E. Coli and Salmonella : absent

Approved by

684 Virginio Busnelli 

S.R.L. - SEDE LEGALE IN MILANO
CAPITALE L. 533.742.617.001 V.
TRIBUNALE DI MILANO R.S. N. 228246
VOL. 6368 - FASC. 46 - C.C.I.A.A. N. 1171077
COD. FISC. E PART. IVA N. 07608290156

GRUPPO ERBAMONT
MONTEDISON - CURA DELLA SALUTE

9550082

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 6995.1 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASSELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA-I

 **FARMITALIA CARLO ERBA**

DATA September 17, 1990

VS. RIF.

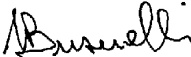
NS. RIF.

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

PLACEBO for Reboxetine 6 mg capsules

Batch SF 1134

Manufacturing date	: September 1990
Description	: hard-gelatin capsule, opaque red-brown, size No. 0, containing three white, round, convex, 6 mm diameter placebo tablets for reboxetine 2 mg, marked S.F. on one surface
Average weight	: 303.64 mg
Uniformity of mass	: complies, according to Eur. Ph., 2nd Ed., requirements
Identification	: negative
Microbial contamination	: total viable aerobic count < 1000 moulds and yeasts < 100 E. Coli and Salmonella : absent
Approved by	: Virginio Busnelli 

685

S.P.A. SEDE LEGALE IN MILANO
CAPITALE L. 533.742.817.000 I.V.
TRIBUNALE DI MILANO R.S. N. 299246
VOL. 6366 - FASC. 46 - C.C.I.A.A. N. 1171077
COD. FISC. E PART. IVA N. 07608240159

GRUPPO ERBAMONT
MONTEDISON CURA DELLA SALUTE

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

9550082

 FARMITALIA CARLO ERBA

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 6995.1 (CENTRALINO)
TELEGRAMMI ERBACAR MILANO
CASSELLA POSTALE 10319
C.C. POSTALE 619205
TELEX 330314 ERBA-I

DATA December 11th, 1991

VS. RIF.

NS. RIF.

TEL DIRETTO

CERTIFICATE OF ANALYSIS

PLACEBO for Reboxetine capsules

Batch SF 1247

Manufacturing date : October, 1991

Appearance : red-brown, hard-gelatin capsule,
snap-fit, size No. 0, containing
two round, convex, 6 mm diameter,
white tablets, marked S.F. on a
side (batch SF 1205)

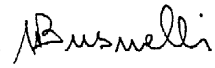
Identification : negative

Average weight : mg 199.76

Uniformity of weight : within the limits, according to Ph.
Eur. 2nd Ed., Section V.5.2.1

Disintegration : 10 minutes

Microbial contamination : total viable aerobic count < 1000
moulds and yeasts < 100
E. Coli and Salmonellae : absent

Approved by : Virginio Busnelli 

686

GRUPPO ERBAMONT

RI - ENE LOGA E P. M. 11/11
CANTIERI 208 - 32 127 0101
TRIBUNALE DI MILANO P.S. N. 238246
VOL. 6366 - FASC. 36 - C.C.I.A.A. N. 1171677
COD. FISC. E PART. IVA N. 07608290156

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

9550082



VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 69951 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASSELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA-I.

DATA May 20th, 1992

VS. RIF.

NS. RIF.

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

PLACEBO for Reboxetine capsules

Batch SF 1306

Manufacturing date	: April, 1992
Appearance	: red-brown, hard-gelatin capsule, snap-fit, size No. 0, containing three round, convex, 6 mm diameter, white tablets, marked S.F. on a side (batch SF 1205)
Identification	: negative
Average weight	: mg 298.27
Uniformity of weight	: within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.1
Disintegration	: 8 minutes
Microbial contamination	: total viable aerobic counts < 1000 moulds and yeasts < 100 E. Coli and Salmonellae : absent

Approved by

: Virginio Busnelli

687

S.R.L. SEDE LEGALE IN MILANO
CAPITALE L. 528.732.127.000 I.V.
TRIBUNALE DI MILANO R.S. N. 238246
VOL. 5266 - FASC. 46 - C.C./A.A. N. 1171077
COD. FISC. E PART. IVA N. 07608290156

GRUPPO ERBAMONT

9550082

VIA CARLO IMBONATI, 24
20159 MILANO
TELEFONO (02) 89951 (CENTRALINO)
TELEGRAMMI ERBACAP-MILANO
CASSELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA I.



DATA October 19, 1990

VS. RIF.

NS. RIF.

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

Imipramine hydrochloride 50 mg capsules

Batch SF 1130

Manufacturing date : September 1990
Expiry date : October 1994
Description : hard-gelatin capsule, opaque red-brown, size No. 0, containing two 25 mg TOFRANIL sugar coated, dark pink orange, tablets (GEIGY, batch No.153)
Average weight : mg 149.443
Uniformity of mass : complies, according to Eur. Ph., 2nd Ed., requirements
Disintegration time : 13 minutes
Microbial contamination : total viable aerobic count < 1000 moulds and yeasts < 100
E. Coli and Salmonella : absent
Approved by : Virginio Busnelli *VB*

688

S.R.L. - SEDE LEGALE IN MILANO
CAPITALE L. 633.742.617.000 I.V.
TRIBUNALE DI MILANO R.S. N. 238246
VOL. 6366 - FASC. 46 - C.C.I.A.A. N. 117/077
COD. FISC. E PART. IVA N. 07608290156

GRUPPO ERBAMONT
MONTEDISON CURA DELLA SALUTE

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

9550082

VIA CARLO IMBONATI, 24
20150 MILANO



FARMITALIA CARLO ERBA

TELEFONO (02) 6995.1 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASELLA POSTALE 10619
C.C. POSTALE 619205
TELEX 330314 ERBA-I

DATA March 24th, 1992

VS. RIF.

NS. RIF.

*EL DIRETTO

CERTIFICATE OF ANALYSIS

Imipramine hydrochloride 50 mg capsules

Batch SF 1265

Manufacturing date : December 1990
Expiry date : December 1995
Description : hard-gelatin capsule, opaque red-brown,
size No.0, containing two 25 mg TOFRANIL
sugar coated, dark pink orange, tablets
(GEIGY, batch No. 178)
Average weight : mg 151.49
Uniformity of mass : complies, according to Eur. Ph., 2nd Ed.,
requirements
Disintegration time : 12 minutes
Identification : positive, according to B.P. 1988
monograph texts A, B and C, page 956
Assay : 48.41 mg/capsule (B.P. 1988 monograph,
page 956)
Related substances : within the limits, according to B.P.1988
monograph, page 956
Microbial contamination : total viable aerobic count < 1000
moulds and yeasts < 100
E. Coli and Salmonellae : absent
Approved by 689 : V. Busnelli *Busnelli*

S.R.L. SEDE LEGALE IN MILANO
CAPITALE L. 528.700.000 IV
TRIBUNALE DI MILANO R.S. N. 238246
VOL. 6368 FASC. 46 - C.C.I.A.A. N. 1171077
COD. FISC. E PART. IVA N. 07608290156

GRUPPO ERBAMONT

9550082

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 69951 (CENTRALINO)
TELEGRAMMI ERBACAR MILANO
CASELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA-I



DATA October 22, 1990

VS. RIF.

NS. RIF.

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

Imipramine hydrochloride 100 mg capsules

Batch SF 1129

Manufacturing date	: September 1990
Expiry date	: October 1994
Description	: hard-gelatin capsule, opaque red-brown, size No. 0, containing four 25 mg TOFRANIL sugar coated, dark pink orange, tablets (GEIGY, batch No.156)
Average weight	: mg 301.251
Uniformity of mass	: complies, according to Eur. Ph., 2nd Ed., requirements
Disintegration time	: 12 minutes
Microbial contamination	: total viable aerobic count < 1000 moulds and yeasts < 100 E. Coli and Salmonella : absent
Approved by	: Virginio Busnelli <i>VB</i>

690

S.F. - SEDE LEGALE IN MILANO
CAPITALE L. 503.742.617.000 I.V.
TRIBUNALE DI MILANO R.S. N. 2382/16
VOL. 6386 - FASC. 48 - C.C.I.A.A. N. 117/1077
COD. FISC. E PART. IVA N. 07606290156

GRUPPO ERBAMONT
MONTEDISON CURA DELLA SALUTE

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9550082

VIA CARLO MONCATTI 24
20159 MILANO

 FARMITALIA CARLO ERBA

TELEFONO (02) 69951 (CENTRALINO)
TELEFAX (02) 69951111
CASSA POSTALE 10579
C.C. POSTALE 618205
TELEX 370314 ERBA I

October 25, 1990

DATA

VS. RIF

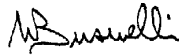
VS. RIF

TEL. DIRETTO

ANALYSIS CERTIFICATE

Imipramine hydrochloride 100 mg capsules

Batch SF 1151

Manufacturing date : October 1990
Expiry date : October 1994
Description : hard-gelatin capsule, opaque red-brown,
size No.0, containing four 25 mg TOFRANIL
sugar coated, dark pink orange, tablets
(GEIGY, batch No. 153)
Average weight : mg 300.63
Uniformity of mass : complies, according to Eur. Ph., 2nd Ed.,
requirements
Disintegration time : 12 minutes
Microbial contamination : total viable aerobic count < 1000
moulds and yeasts < 100
E. coli and Salmonella : absent
APPROVED BY : Virginio Busnelli 

691

S.R.L. - SEDE LEGALE IN MILANO
CAPITALE L. 233.742.617.000 IV
TRIBUNALE DI MILANO R.S. N. 238248
VOL. 6968 - FASC. 48 - C.C.I.A.A. N. 117/077
COD. FISC. E PART. IVA N. 07608290156

GRUPPO ERBAMONT
MONTEDISON CURA DELLA SALUTE

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

9550082

VIA CARLO IMBONATI, 24
20159 MILANO



TELEFONO (02) 6995.1 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASSELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 930314 ERBA-I-

DATA March 24th, 1992

VS. RIF.

NS. RIF.

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

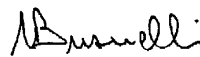
Imipramine hydrochloride 100 mg capsules

Batch SF 1263

Manufacturing date : December 1990
Expiry date : December 1995
Description : hard-gelatin capsule, opaque red-brown,
size No.0, containing four 25 mg TOFRANIL
sugar coated, dark pink orange, tablets
(GEIGY, batch No. 178)
Average weight : mg 299.87
Uniformity of mass : complies, according to Eur. Ph., 2nd Ed.,
requirements
Disintegration time : 12 minutes
Identification : positive, according to B.P. 1988
monograph texts A, B and C, page 956
Assay : 95.43 mg/capsule (B.P. 1988 monograph,
page 956)
Related substances : within the limits, according to B.P.1988
monograph, page 956.
Microbial contamination : total viable aerobic count < 1000
moulds and yeasts < 100
E. Coli and Salmonellae : absent

Approved by

692

: V. Busnelli 

S.R.L. - SEDE LEGALE IN MILANO
CAPITALE L. 528.732.127.000 IV
TRIBUNALE DI MILANO R.S. N. 238246
VOL. 6366 - FASC. 46 - C.C.I.A.A. N. 1171077
COD. FISC. E PART. IVA N. 07608290156

GRUPPO ERBAMONT

9550082

Pharmacia

Document 9550082

12.1.6 AUDIT CERTIFICATE

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

9550082

Pharmacia & Upjohn
PPC Italy / GCP-Quality Assurance

R&D/Q.A. AUDIT CERTIFICATE

Product **REBOXETINE**

Protocol N°: **FCE 20124/015** N° GCP: **44**

Study title: **Multicenter, multinational double-blind study of the activity and tolerability of Reboxetine vs Imipramine and placebo in patients suffering from Major Depressive Episodes.**

Type of Audit	Site	Audit date(s)	Reporting date
Draft Protocol	FICE - Milan	04.05.1990	21.05.1990
Final Protocol	FICE - Milan	08.1990	28.08.1990
Study Master File	Pharmacia - Milan	11.02.1992	24.02.1992
Audit at CRO-ACRS	Germany	07.05.1992	20.05.1992
Study Master File	Pharmacia - Milan	04-05.05.1993	20.05.1993
Investigator Site	Centre N°9 (Italy)	28.06.1993	05.07.1993
Investigator Site	Centre N°8 (Italy)	30.09.1993	15.10.1993
Study Master File	Pharmacia - Milan	08-15.02.1995	16.02.1995
Draft Final Report	Pharmacia - Milan	05-19.12.1995	08.01.1996
Final Report	Pharmacia - Milan	13.03.1996	13.03.1996

Signature of the Head of PPC Italy/GCP-Q.A. Q. Meave

Date: March 13th, 1996

Pharmacia

Document 9550082

12.1.7 RANDOMISATION LIST

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

REBOXETINE - PROT 955082
RANDOMIZATION LIST

8:46 Friday, September 14, 1990

----- CENTRE=1 AUSTRALIA -----

PTS N.	TREATMENT
1	imipramine
2	reboxetine
3	imipramine
4	placebo
5	reboxetine
6	placebo
7	reboxetine
8	placebo
9	reboxetine
10	placebo
11	imipramine
12	imipramine
13	placebo
14	placebo
15	imipramine
16	imipramine
17	reboxetine
18	reboxetine
19	reboxetine
20	imipramine
21	imipramine
22	placebo
23	reboxetine
24	placebo
25	reboxetine
26	placebo
27	imipramine
28	reboxetine
29	placebo
30	imipramine

REBOXETINE - PROT. 955082
RANDOMIZATION LIST

8:46 Friday, September 14, 1990

----- CENTRE=2 FRANCE -----

PTS N.	TREATMENT
31	placebo
32	reboxetine
33	imipramine
34	placebo
35	reboxetine
36	imipramine
37	reboxetine
38	placebo
39	imipramine
40	reboxetine
41	placebo
42	imipramine
43	imipramine
44	imipramine
45	reboxetine
46	placebo
47	placebo
48	reboxetine
49	placebo
50	reboxetine
51	imipramine
52	imipramine
53	placebo
54	reboxetine
55	reboxetine
56	reboxetine
57	imipramine
58	placebo
59	placebo
60	imipramine

REBOXETINE - PROT. 015
RANDOMIZATION LIST

8:46 Friday, September 14, 1990

10U

----- CENTRE=3 FRANCE -----

PTS N.	TREATMENT
61	imipramine
62	imipramine
63	placebo
64	placebo
65	reboxetine
66	reboxetine
67	placebo
68	reboxetine
69	placebo
70	imipramine
71	imipramine
72	reboxetine
73	placebo
74	reboxetine
75	imipramine
76	imipramine
77	placebo
78	reboxetine
79	imipramine
80	imipramine
81	reboxetine
82	placebo
83	placebo
84	reboxetine
85	imipramine
86	imipramine
87	placebo
88	placebo
89	reboxetine
90	reboxetine

REBOXETINE - PROT. 9550082
RANDOMIZATION LIST

8:46 Friday, September 14, 1990

----- CENTRE=4 FRANCE -----

PTS N.	TREATMENT
91	imipramine
92	reboxetine
93	placebo
94	placebo
95	imipramine
96	reboxetine
97	placebo
98	reboxetine
99	placebo
100	imipramine
101	imipramine
102	reboxetine
103	imipramine
104	reboxetine
105	placebo
106	imipramine
107	placebo
108	reboxetine
109	reboxetine
110	imipramine
111	imipramine
112	placebo
113	reboxetine
114	placebo
115	reboxetine
116	imipramine
117	imipramine
118	reboxetine
119	placebo
120	placebo

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082

8:46 Friday, September 14, 1990

----- CENTRE=5 FRANCE -----

PIS N.	TREATMENT
121	imipramine
122	placebo
123	imipramine
124	placebo
125	reboxetine
126	reboxetine
127	reboxetine
128	reboxetine
129	placebo
130	placebo
131	imipramine
132	imipramine
133	placebo
134	reboxetine
135	imipramine
136	imipramine
137	reboxetine
138	placebo
139	imipramine
140	placebo
141	placebo
142	imipramine
143	reboxetine
144	reboxetine
145	imipramine
146	placebo
147	reboxetine
148	imipramine
149	reboxetine
150	placebo

REBOXETINE - PROT. 015
RANDOMIZATION LIST 550082

8:46 Friday, September 14, 1990

----- CENTRE=6 FRANCE -----

PTS N.	TREATMENT
151	imipramine
152	reboxetine
153	reboxetine
154	imipramine
155	placebo
156	placebo
157	reboxetine
158	imipramine
159	imipramine
160	placebo
161	reboxetine
162	placebo
163	reboxetine
164	imipramine
165	imipramine
166	reboxetine
167	placebo
168	placebo
169	imipramine
170	placebo
171	imipramine
172	reboxetine
173	placebo
174	reboxetine
175	imipramine
176	placebo
177	imipramine
178	reboxetine
179	placebo
180	reboxetine

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082

8:46 Friday, September 14, 1990

----- CENTRE=7 GERMANY -----

PTS N.	TREATMENT
181	reboxetine
182	placebo
183	imipramine
184	imipramine
185	reboxetine
186	placebo
187	imipramine
188	placebo
189	placebo
190	reboxetine
191	imipramine
192	reboxetine
193	placebo
194	reboxetine
195	placebo
196	reboxetine
197	imipramine
198	imipramine
199	imipramine
200	placebo
201	reboxetine
202	reboxetine
203	placebo
204	imipramine
205	placebo
206	imipramine
207	imipramine
208	reboxetine
209	placebo
210	reboxetine

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082

8:46 Friday, September 14, 1990

----- CENTRE=8 ITALY -----

PTS N.	TREATMENT
211	reboxetine
212	placebo
213	imipramine
214	reboxetine
215	placebo
216	imipramine
217	reboxetine
218	reboxetine
219	placebo
220	imipramine
221	imipramine
222	placebo
223	imipramine
224	placebo
225	placebo
226	reboxetine
227	reboxetine
228	imipramine
229	imipramine
230	reboxetine
231	imipramine
232	reboxetine
233	placebo
234	placebo
235	placebo
236	placebo
237	reboxetine
238	reboxetine
239	imipramine
240	imipramine

REBOXETINE - PROT. 9550082
RANDOMIZATION LIST

8:46 Friday, September 14, 1990

----- CENTRE=9 ITALY -----

PTS N.	TREATMENT
241	placebo
242	reboxetine
243	reboxetine
244	imipramine
245	imipramine
246	placebo
247	placebo
248	placebo
249	reboxetine
250	imipramine
251	imipramine
252	reboxetine
253	reboxetine
254	imipramine
255	reboxetine
256	imipramine
257	placebo
258	placebo
259	reboxetine
260	imipramine
261	placebo
262	reboxetine
263	imipramine
264	placebo
265	imipramine
266	reboxetine
267	placebo
268	reboxetine
269	imipramine
270	placebo
271	reboxetine
272	placebo
273	imipramine
274	reboxetine
275	placebo
276	imipramine
277	placebo
278	imipramine
279	reboxetine
280	reboxetine
281	imipramine
282	placebo
283	reboxetine
284	placebo
285	imipramine
286	placebo
287	reboxetine
288	imipramine

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082

8:46 Friday, September 14, 1990

----- CENTRE=10 SWEDEN -----

PTS N.	TREATMENT
289	placebo
290	placebo
291	imipramine
292	reboxetine
293	imipramine
294	reboxetine
295	placebo
296	reboxetine
297	imipramine
298	reboxetine
299	imipramine
300	placebo
301	reboxetine
302	reboxetine
303	placebo
304	imipramine
305	imipramine
306	placebo
307	reboxetine
308	imipramine
309	reboxetine
310	placebo
311	imipramine
312	placebo
313	reboxetine
314	imipramine
315	placebo
316	placebo
317	imipramine
318	reboxetine

REBOXETINE - PROT. 045
RANDOMIZATION LIST 9550082

8:46 Friday, September 14, 1990

----- CENTRE=11 U.K. -----

PTS N.	TREATMENT
319	placebo
320	imipramine
321	placebo
322	reboxetine
323	reboxetine
324	imipramine
325	reboxetine
326	placebo
327	imipramine
328	imipramine
329	placebo
330	reboxetine
331	imipramine
332	reboxetine
333	placebo
334	reboxetine
335	placebo
336	imipramine
337	reboxetine
338	imipramine
339	imipramine
340	reboxetine
341	placebo
342	placebo
343	imipramine
344	placebo
345	reboxetine
346	imipramine
347	reboxetine
348	placebo
349	imipramine
350	imipramine
351	reboxetine
352	placebo
353	placebo
354	reboxetine
355	imipramine
356	reboxetine
357	placebo
358	imipramine
359	reboxetine
360	placebo
361	imipramine
362	reboxetine
363	imipramine
364	placebo
365	reboxetine
366	placebo

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082
12:38 Tuesday, September 18, 1990

----- CENTRE=12 CANADA -----

PTS N.	TREATMENT
367	reboxetine
368	placebo
369	imipramine
370	placebo
371	imipramine
372	reboxetine
373	reboxetine
374	placebo
375	imipramine
376	reboxetine
377	imipramine
378	placebo
379	imipramine
380	reboxetine
381	imipramine
382	reboxetine
383	placebo
384	placebo
385	placebo
386	imipramine
387	reboxetine
388	placebo
389	imipramine
390	reboxetine
391	imipramine
392	imipramine
393	placebo
394	placebo
395	reboxetine
396	reboxetine
397	reboxetine
398	imipramine
399	placebo
400	placebo
401	imipramine
402	reboxetine

707

189550082, March 11, 1991

REBOXETINE - PROT. 015
RANDOMIZATION LIST

----- CENTRE=1 b AUSTRALIA -----

PTS N.	TREATMENT
403	imipramine
404	reboxetine
405	placebo
406	imipramine
407	reboxetine
408	placebo
409	reboxetine
410	placebo
411	imipramine
412	reboxetine
413	placebo
414	imipramine
415	imipramine
416	reboxetine
417	imipramine
418	placebo
419	placebo
420	reboxetine
421	imipramine
422	imipramine
423	placebo
424	reboxetine
425	placebo
426	reboxetine
427	imipramine
428	reboxetine
429	placebo
430	reboxetine
431	imipramine
432	placebo

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082 Tuesday, May 14, 1991

-----CENTRE-2 FRANCE BIS-----

PTS N.	TREATMENT
433	reboxetine
434	reboxetine
435	placebo
436	imipramine
437	placebo
438	imipramine
439	placebo
440	reboxetine
441	imipramine
442	reboxetine
443	imipramine
444	placebo
445	placebo
446	reboxetine
447	reboxetine
448	imipramine
449	imipramine
450	placebo

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082 Tuesday, May 14, 1991

----- CENTRE=3 FRANCE BIS -----

ITS N.	TREATMENT
451	reboxetine
452	placebo
453	imipramine
454	reboxetine
455	placebo
456	imipramine
457	placebo
458	reboxetine
459	placebo
460	reboxetine
461	imipramine
462	imipramine
463	reboxetine
464	imipramine
465	imipramine
466	reboxetine
467	placebo
468	placebo

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082 Tuesday, May 14, 1991

-----CENTRE=4 FRANCE BIE-----

PTS N.	TREATMENT
469	imipramine
470	reboxetine
471	placebo
472	reboxetine
473	placebo
474	imipramine
475	reboxetine
476	placebo
477	imipramine
478	imipramine
479	reboxetine
480	placebo
481	placebo
482	imipramine
483	imipramine
484	reboxetine
485	reboxetine
486	placebo

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082 9:46 Tuesday, May 14, 1991

----- CENTRE=5 FRANCE BIS -----

PTS N.	TREATMENT
487	imipramine
488	reboxetine
489	imipramine
490	placebo
491	placebo
492	reboxetine
493	reboxetine
494	placebo
495	imipramine
496	placebo
497	reboxetine
498	imipramine
499	reboxetine
500	imipramine
501	imipramine
502	placebo
503	reboxetine
504	placebo

REBOXETINE - PROT. 015
RANDOMIZATION LIST 9550082
9550082 Tuesday, May 14, 1991

-----CENTRE-6 FRANCE BIS-----

PTE N.	TREATMENT
505	imipramine
506	placebo
507	imipramine
508	reboxetine
509	placebo
510	reboxetine
511	imipramine
512	placebo
513	imipramine
514	reboxetine
515	placebo
516	reboxetine
517	reboxetine
518	reboxetine
519	placebo
520	imipramine
521	imipramine
522	placebo

9550082
REBOXETINE - PROT. 015
RANDOMIZATION LIST

----- CENTRE=7 GERMANY BIS -----

PTS N.	TREATMENT
523	reboxetine
524	placebo
525	placebo
526	reboxetine
527	imipramine
528	imipramine
529	placebo
530	imipramine
531	reboxetine
532	imipramine
533	reboxetine
534	placebo
535	placebo
536	reboxetine
537	imipramine
538	reboxetine
539	imipramine
540	placebo
541	reboxetine
542	imipramine
543	imipramine
544	placebo
545	placebo
546	reboxetine
547	placebo
548	placebo
549	reboxetine
550	reboxetine
551	imipramine
552	imipramine

714

REBOXETINE - PROT. 015 9550082
RANDOMIZATION LIST

----- CENTRE=8 ITALY BIS -----

PTS N.	TREATMENT
553	placebo
554	reboxetine
555	reboxetine
556	imipramine
557	placebo
558	imipramine
559	reboxetine
560	imipramine
561	placebo
562	placebo
563	imipramine
564	reboxetine
565	placebo
566	reboxetine
567	imipramine
568	reboxetine
569	imipramine
570	placebo
571	placebo
572	imipramine
573	reboxetine
574	imipramine
575	reboxetine
576	placebo
577	reboxetine
578	imipramine
579	imipramine
580	placebo
581	reboxetine
582	placebo

9550082

Pharmacia

Document 9550082

12.1.8 CRITERIA USED TO JUDGE LABORATORY ABNORMALITIES AS
CLINICALLY RELEVANT AND REFERENCE VALUES FOR LABORATORY
TESTS

716

9550082

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PHARMACIA CNS R&D

REBOVETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.8

CRITERIA USED TO JUDGE LABORATORY ABNORMALITIES AS CLINICALLY RELEVANT

Laboratory test	Percent variation above or below normal range (*)
HB	- 15
HT	- 15
RBC	- 15
PLATELETS	- 30
WBC	+ 30
WBC: N	+ 30
WBC: E	+ 30
WBC: B	+ 30
WBC: L	+ 30
WBC: M	+ 30
CREATININE	+ 50
UREA	+ 50
BUN	+ 50
URIC ACID	+ 50
TOT. PROTEINS	+ 30
ALBUMINE	+ 30
TOT BILIRUBIN	+ 100
DIR BILIRUBIN	+ 100
SGPT	+ 100
SGPT	+ 100
GAMMA GT	+ 100
LDH	+ 100
ALK. PHOSPH.	+ 100
GLOBULINS ALPHA 1	+ 30
GLOBULINS ALPHA 2	+ 30
GLOBULINS BETA	+ 30
GLOBULINS GAMMA	+ 30
TOT. CHOLEST.	+ 30
HDL	- 20
TRIGLYCERIDES	+ 30
GLUCOSE	+ 30
NA+	+ 10
CL-	+ 10
K+	+ 15
Ca++	+ 15
PO4--	+ 15
PT3	not defined
T3	not defined
T4	not defined
TSH	not defined
ESR/SEDIMENT. RATE	not defined

(*) MINUS INDICATES BELOW THE LOWER LIMIT OF NORMAL RANGE, AND PLUS ABOVE THE UPPER LIMIT OF NORMAL RANGE

PHARMACIA CNS 9550082
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.8
 LABORATORY REFERENCE VALUES

		Range values			
		Female		Male	
		Min	Max	Min	Max
Laboratory test	Units				
HB	g/dl	12.00	16.00	13.50	17.50
HT	%	36.00	46.00	41.00	53.00
RBC	10 ⁶ /mm ³	4.00	5.20	4.50	5.90
PLATELETS	10 ³ /mm ³	150.00	400.00	150.00	400.00
ESR/SEDIMENT. RATE 1st h	mm	0.00	10.00	0.00	10.00
ESR/SEDIMENT. RATE 2nd h	mm	0.00	20.00	0.00	20.00
WBC	10 ³ /mm ³	4.50	11.00	4.50	11.00
WBC: N	%	57.00	67.00	57.00	67.00
WBC: E	%	1.00	3.00	1.00	3.00
WBC: B	%	0.00	0.75	0.00	0.75
WBC: L	%	23.00	33.00	23.00	33.00
WBC: M	%	3.00	7.00	3.00	7.00
CREATININE	mg/dl	0.50	1.10	0.60	1.20
CREATININE CLEARANCE	ml/min	88.00	128.00	97.00	137.00
UREA	mg/dl	15.00	35.00	15.00	35.00
BUN	mg/dl	7.00	18.00	7.00	18.00
URIC ACID	mg/dl	2.60	6.00	3.50	7.20
TOT. PROTEINS	g/dl	6.40	8.30	6.40	8.30
ALBUMINE	g/dl	3.50	5.00	3.50	5.00
TOT BILIRUBIN	mg/dl	0.20	1.00	0.20	1.00
DIR BILIRUBIN	mg/dl	0.00	0.20	0.00	0.20
SGOT	U/l	10.00	30.00	10.00	30.00
SGPT	U/l	5.00	30.00	5.00	30.00
GAMMA GT	U/l	8.00	40.00	9.00	50.00
LDH	U/l	210.00	420.00	210.00	420.00
ALK. PHOSPH.	U/l	56.00	155.00	62.00	176.00
GLOBULINS ALPHA 1	g/dl	0.10	0.30	0.10	0.30
GLOBULINS ALPHA 2	g/dl	0.60	1.00	0.60	1.00
GLOBULINS BETA	g/dl	0.70	1.10	0.70	1.10
GLOBULINS GAMMA	g/dl	0.80	1.60	0.80	1.60
SEDIMENT.	mm/h	0.00	20.00	0.00	15.00
TOT. CHOLEST.	mg/dl	152.00	268.00	158.00	276.00
HDL	mg/dl	35.00	65.00	29.00	60.00
TRIGLYCERIDES	mg/dl	38.00	160.00	49.00	284.00
GLUCOSE	mg/dl	70.00	105.00	70.00	105.00
NA+	mEq/l	136.00	146.00	136.00	146.00
CL-	mEq/l	98.00	106.00	98.00	106.00
K+	mEq/l	3.50	5.10	3.50	5.10
Ca++	mEq/l	4.50	5.50	4.50	5.50
PO4--	mEq/l	1.00	1.50	1.00	1.50
T4	ug/dl	5.00	12.00	5.00	12.00
TSH	mU/l	2.00	10.00	2.00	10.00

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Pharmacia

Document 9550082

12.1.9 ADVERSE EVENTS GROUPED IN CLUSTERS

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20324/015
Appendix No.: 12.1.9

ADVERSE EVENTS GROUPED IN CLUSTERS

Body System	Cluster	Adverse event	Treatment	No of AE	No of Pt with AE	
BODY AS A WHOLE-GENERAL DISORDERS	ASTHENIA / FATIGUE	ASTHENIA	Imipramine	3	3	
		ASTHENIA	Reboxetine	1	1	
		FATIGUE	Imipramine	4	4	
		FATIGUE	Placebo	4	4	
		FATIGUE	Reboxetine	3	3	
CARDIOVASCULAR DISORDERS, GENERAL	CARDIAC ISCHEMIA AND RELATED SYMPTOMS FLUSHING / HOT FLASHING HYPOTENSION AND RELATED SYMPTOMS	CHEST PAIN PRECORDIAL	Imipramine	2	2	
		CHEST PAIN PRECORDIAL	Placebo	1	1	
		FLUSHING	Reboxetine	1	1	
		HOT FLUSHES	Imipramine	4	4	
		HOT FLUSHES	Placebo	1	1	
		HOT FLUSHES	Reboxetine	1	1	
		DIZZINESS	Imipramine	16	14	
		DIZZINESS	Placebo	4	4	
		DIZZINESS	Reboxetine	4	4	
		HYPOTENSION	Imipramine	1	1	
		HYPOTENSION	Placebo	2	2	
		HYPOTENSION	Reboxetine	2	2	
		HYPOTENSION POSTURAL	Imipramine	6	6	
		HYPOTENSION POSTURAL	Reboxetine	2	2	
SYNCOPE	Imipramine	2	2			
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	HEADACHE / MIGRAINE	HEADACHE	Imipramine	9	9	
		HEADACHE	Placebo	10	9	
		HEADACHE	Reboxetine	18	14	
		MIGRAINE	Reboxetine	1	1	
GASTRO-INTESTINAL SYSTEM DISORDERS	NAUSEA AND RELATED SYMPTOMS	VOMITING	Imipramine	1	1	
		VOMITING	Placebo	4	4	
		VOMITING	Reboxetine	1	1	
		DYSPEPSIA	Imipramine	5	5	
		DYSPEPSIA	Placebo	1	1	
		GASTRITIS	Reboxetine	1	1	
		NAUSEA	Imipramine	16	13	
		NAUSEA	Placebo	11	5	
		NAUSEA	Reboxetine	9	9	
HEMATOLOGY DISORDERS	ANEMIA	Imipramine	1	1		
LIVER AND BILIAR SYSTEM DISORDERS	INCREASED LIVER ENZYMES	GAMMA-GT INCREASED	Imipramine	1	1	
		GAMMA-GT INCREASED	Reboxetine	1	1	
PSYCHIATRIC DISORDERS	AGITATION / ANXIETY / NERVOUSNESS	AGITATION	Imipramine	4	4	
		AGITATION	Placebo	7	7	
		AGITATION	Reboxetine	8	7	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Appendix No.: 12.1.9

ADVERSE EVENTS GROUPED IN CLUSTERS

Body System	Cluster	Adverse event	Treatment	No of AE	No of Pt with AE
PSYCHIATRIC DISORDERS	AGITATION / ANXIETY / NERVOUSNESS	ANXIETY	Imipramine	1	1
		ANXIETY	Placebo	3	3
		ANXIETY	Reboxetine	1	1
		NERVOUSNESS	Placebo	1	1
SKIN AND APPENDAGES DISORDERS	ERYTHEMA / RASH	NERVOUSNESS	Reboxetine	4	4
		RASH	Imipramine	1	1
		RASH	Placebo	2	2
		RASH ERYTHEMATOUS	Reboxetine	1	1
URINARY SYSTEM DISORDERS	URINARY HESITANCY / RETENTION	URINARY RETENTION	Placebo	1	1
		URINARY RETENTION	Reboxetine	3	3
		MICTURITION DISORDER	Imipramine	1	1
		MICTURITION DISORDER	Placebo	1	1
VISION DISORDERS	BLURRED VISION	MICTURITION DISORDER	Reboxetine	3	3
		ACCOMMODATION ABNORMAL	Imipramine	1	1
		VISION ABNORMAL	Imipramine	10	9
		VISION ABNORMAL	Placebo	3	3
		VISION ABNORMAL	Reboxetine	7	6

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9550082

Pharmacia

Document 9550082

12.1.10 ECG CODES

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722

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20020062

APPENDIX No.: 12.1.10

ECG CODES

0 Normal

1 Rhythm disorders

- 10 Sinus bradycardia (<60)
- 20 Sinus tachycardia (>100)
- 30 Sick Sinus Syndrome
- 40
 - Atrial ectopic beats:
 - 41 - Occasional
 - 42 - Frequent (>6/mm)
 - 43 - Couplets
 - 44 - Supraventricular Tachycardia
- 50
 - Ventricular ectopic beats:
 - 51 - Occasional
 - 52 - Frequent (>6/mm)
 - 53 - Polymorphic
 - 54 - Couplets
 - 55 - Ventricular Tachycardia
- 60
 - Atrial fibrillation/flutter
- 105
 - Vagotonia
- 108
 - Atrial-ventricular dissociation

2 Conduction disorders

- 70
 - A-V Block
 - 71 - 1st degree
 - 72 - 2nd degree - Mobitz 1
 - 73 - Complete - Mobitz 2
- 85
 - Right bundle branch block
- 86
 - Left bundle branch block
- 87
 - Left anterior hemiblock
- 88
 - Left posterior hemiblock
- 89
 - Bifascicular Block (specify)
- 90
 - Trifascicular Block (specify)
- 91
 - Conduction disorders
- 103
 - Left axial deviation
- 106
 - Right incomplete bundle branch block

3 Ischemic signs

- 102
 - Repolarization disturbances
- 107
 - Non specific ST-T changes
- 82
 - Myocardial ischemia
- 84
 - Acute Myocardial infarction

4 Other

- 80
 - Left ventricular hypertrophy
- 81
 - Right ventricular hypertrophy
- 83
 - Previous Myocardial infarction
- 93
 - Other (specify) _____
- 104
 - Right axial deviation

723

9550082

Pharmacia

Document 9550082

12.1.11 STATISTICAL ANALYSIS PROGRAMS LISTINGS

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```

*
*          PHARMACIA CNS R&D          9550082
*
*          APPENDIX No.: 12.1.11
*
*-----*
* PGM NAME: LAB003
* CREATED: 07.12.93
* AIM : Stuart-Maxwell test
*
* BY CORTESI - PANSID MI
*-----*

%macro labstat(var= );
proc sort data = labst;
  by centre patient lab_par day;

data stat(keep = lab_par day lab_ind lab_dif &var
           cod_trt bas nr_paz nvis num_ord)
  shift(keep = lab_par day &var cod_trt num_ord
        lab_bas lab_now k up down same nvis)
  maxw (keep = lab_par day &var cod_trt
        indice k nvis num_ord);

set labst;
by centre patient lab_par day ;
retain bas lab_bas 0;
if first.patient then nr_paz = 1;
else nr_paz = 0;
if first.lab_par then do;
  bas = lab_ind;
  lab_bas = lab_uid;
  lab_dif = .;
end;
else do;
  k = 1;
  lab_now = lab_uid;
  lab_dif =lab_ind - bas;
  up = 0;
  down = 0;
  same = 0;
  if lab_dif > 0 then up = 1;
  else if lab_dif < 0 then down = 1;
  else same = 1;
  output shift;
  indice = (lab_bas-1) * 3 + (lab_now);
  output maxw;
end;
output stat;

* proc univariate * ;

proc sort data = stat;
  by &var cod_trt lab_par day;

proc univariate data = stat noprint;
  by &var cod_trt lab_par day;
  var lab_ind lab_dif bas;
  id num_ord;
  output out =stat (drop=x2-x8 y1-y5)
    mean =lab_mean x2 bas_mean
    median=lab_medi dif_medi bas_medi
    std =lab_std x3 bas_std
    min =lab_min x4 y1
    max =lab_max x5 y2
    n =lab_frq x6 y3
    probt =x7 t_prob y4
    probs =x8 s_prob y5;

proc sort data = shift ;
  by &var cod_trt lab_par day lab_bas lab_now;

proc means data = shift noprint;
  by &var cod_trt lab_par day;
  var up down same;
  id num_ord;
  output out=shifts
    sum=up down same;

```

```

data stat ;
merge stat (in=a) shifts(in=b);
by &var cod_trt lab_par day;
if a = 1 or b = 1;
if b=1 then do;
    if up = down then p_value = 1;
    else p_value = 2. * (probbnml(.5,sum(up,down),min(up,down)));
end;

p_test = s_prob;

*-----*
* MAXWELL TEST *
*-----*

proc sort data = maxw ;
by &var cod_trt lab_par day indice;

proc means data = maxw noprint;
by &var cod_trt lab_par day indice;
var k;
id num_ord;
output out=maxw
sum=k;

data maxw(keep = &var cod_trt lab_par day p_maxw num_ord);
set maxw;
by &var cod_trt lab_par day indice;
retain a11 a12 a13 a21 a22 a23 a31 a32 a33;
array _a_ (9) a11 a12 a13 a21 a22 a23 a31 a32 a33;

if first.day then do i=1 to 9; _a_(i) = 0 ; end;

_a_(indice)=k;
if last.day then do;
    n12=(a12+a21)/2;
    n13=(a13+a31)/2;
    n23=(a23+a32)/2;

    d1=a12+a13-a21-a31;
    d2=a21+a23-a12-a32;
    d3=a31+a32-a13-a23;

    d1=d1*d1;
    d2=d2*d2;
    d3=d3*d3;

    numx2=n23*d1+n13*d2+n12*d3;
    denx2=(n12*(n13+n23)+n13*n23)*2;
    if denx2 > 0 then do;
        x2=numx2/denx2;
        p_maxw = 1 - probchi(x2,2);
    end;
else do;
    if a32 > 0 or a23 > 0 then do;
        if a32 = a23 then p_maxw = 1;
        else do;
            denx2=a32+a23;
            numx2=min(a32,a23);
            p_maxw = 2. * probbnml(0.5,denx2,numx2);
        end;
    end; * if a32 > 0 ..... ;
else if a21 > 0 or a12 > 0 then do;
    if a21 = a12 then p_maxw = 1;
    else do;
        denx2=a21+a12;
        numx2=min(a21,a12);
        p_maxw = 2. * probbnml(0.5,denx2,numx2);
    end;
end; * if a21 > 0 ..... ;
else if a31 > 0 or a13 > 0 then do;
    if a31 = a13 then p_maxw = 1;
    else do;
        denx2=a31+a13;
        numx2=min(a31,a13);
        p_maxw = 2. * probbnml(0.5,denx2,numx2);
    end;
end; * if a31 > 0 ..... ;
else p_maxw = 1; * tutti gli elementi no su diag.;
end; * if denx2 <= 0 ..... ;
output;
end; * if last day ..... ;

proc means data = shift noprint;
by &var cod_trt lab_par day lab_bas lab_now;
var k;
id num_ord;
output out=shift
sum=k;

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9550082

726

```
data maxw (keep = &var cod_trt lab_par day p_maxw maxw_p num_ord
              dw sm up k lab_bas);;          9550082
merge shift(in=a) maxw(in=b);
by &var cod_trt lab_par day;
retain maxw_p;
if first.day then maxw_p = .;
dw = .; sm = .; up = .;
array now (3) dw sm up;
now(lab_now) = k;
output;
if last.day then do;
  * generazione di tutti i possibili incroci (con valori a zero);
  dw = .; sm = .; up = .; k = .;
  lab_bas = 1; output;
  lab_bas = 2; output;
  lab_bas = 3;
  maxw_p = p_maxw;
  output;
end;
run;

%mend labstat;
```



```

PHARMACIA CNS R&D                                9550082
APPENDIX NO. : 12.1.11
*-----*
* PGM NAME: tav50var                               *
* CREATED: 16.05.95                                *
* AIM : MEAN DECREASE OF HAMILTON TOTAL SCORE     *
*       AT LAST ASSESSMENT WITH RESPECT TO BASELINE *
*       AND 95% CONFIDENCE INTERVAL                *
*       USING OUTPUT OF ANOVA                      *
*-----*
* BY CORTESI - PANSID MI                           *
*-----*

options pageno=1;

options pageno=1;
proc glm data=last outstat=sta noprint;
TITLE7 'ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE'
      ' AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE';
class cod_trt;
model diffn=cod_trt;
lsmeans cod_trt /out=med;
run;

data sta;
set sta;
where _source_='ERROR';
tt=abs(tinv(0.025,df));

proc sort data=sta;
by _name_;

proc sort data=med;
by _name_;

data tot;
merge sta med;
by _name_;

limi=lsmean-tt*stderr;
lims=lsmean+tt*stderr;

proc print data = tot;
var cod_trt lsmean tt limi lims;

proc sort data=tot;
by cod_trt;

%let gmaxlev = 0.5;
%let gmaxval = 5;
%let gminval = 25;
%let gbyval = 5;

data graf(keep=cod_trt level value);
set tot end=fine;
by cod_trt;
retain level 0 maxv_minv_difval_;
array dati (3) limi lsmean lims;

if limi < minv_ or minv_ = . then minv_ = limi;
if lims > maxv_ then maxv_ = lims;
x_ = lims - limi;
if x_ > difval_ then difval_ = x_;

level=level + 0.1;
do _i_ = 1 to 3;
value = dati(_i_);
output;
end;
if fine then do;
difval_ =abs(difval_)+1;
minv_ = minv_ - difval_ ;
if minv_ < 0 then minv_ = 0;
maxv_ = maxv_ + difval_ ;
gby_ = abs((maxv_ - minv_) * 0.1);
* if gby_ < 1 then gby_ = 1;
call symput('gmaxlev',put(level+0.1,4.1));
call symput('gminval',put(minv_,4.));
call symput('gmaxval',put(maxv_,4.));
call symput('gbyval',put(gby_,4.));
end;

proc sort data = graf;
by level;
RUN;

728
options reset=global gunit=pct /*rotate=landscape */

```

```

rotate=portrait
device=gddmfam4 gddmtoken=fine240 gddmnickname=59382
vsize= hsize= 7 in hpos= vpos=
vorigin=1.25 in hororigin=2.25 in
ftext=swiss htitle=3 htext=2 display;
RUN;

%include pgmgen(gttitle);
%include pgmgen(gsymbol4);

title5 f=swiss h=2.5
'MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT';
TITLE6 F=SWISS H=2.5 'POINT ESTIMATES AND CONFIDENCE INTERVALS';
title7 ' ' ;

data b;
set graf;
format function $8. text $8. x y 8.4 ;
function='label';
position='3';
size=3 ;
style='swiss';
hsys = '1';
xsys = '2';
ysys = '2';
when= 'a';

x=value;
y=level;
text=put(value,4.1);
RUN;

axis1 label =(a=90 ' ' )
style=0
offset=(2 )
order=0 to &gmaxlev by 0.1
value=none
minor=none
major=none;

axis2 label =(f=swiss h=1.8 ' ' )
value=(f=swiss h=1.5)
minor=none
order=&gminval to &gmaxval by &gbyval;

legend1 label =none
frame
value=(f=swiss h=2.0)
position=(bottom center outside);

* legend1 label =(position=top f=swiss h=1.8 'Treatments:')
down=5
value=(f=swiss h=2.0);

proc gplot data=graf;
plot level*value=cod_trt /
annotate=b
vaxis=axis1
haxis=axis2
legend=legend1;
format cod_trt $ftrt.;
run;

proc sort data = med;
by descending cod_trt;

data med1(keep=trt_con dif ls li er);
set med end=fine;
retain m1-m10 st1-st10 i 0 ;
format trt1-trt10 $8. trt_con $30.;
retain trt1-trt10;
array tmean (10) m1-m10;
array tstd (10) st1-st10;
array trt (10) trt1-trt10;
i = i + 1;
file print;
if i > 10 then
put 'MORE THAN 10 TREATMENTS '
'delle array ' i= trt1= trt2= trt3= trt4= trt5= trt6=
trt7= trt8= trt9= trt10=;

else do;
ttrt(i) = cod_trt;
tmean(i) = lsmean;
tstd(i) = stderr;
end;
if fine=i then do;
da = 0;
DO K = 1 TO I - 1; * MAX NUMBER OF TREATMENTS ;

```

```
do da = k + 1 to i;
  trt_con = trim(put(ttrt(k), $ftrt.))||' - '||
            trim(put(ttrt(da), $ftrt.));
  dif = tmean(k) - tmean(da);
  er=sqrt(tstd(k)**2+tstd(da)**2);
  ls=dif+1.96*er;
  li=dif-1.96*er;
  output;
end;
end;
label trt_con='Treatments'
      dif='means difference'
      li='lower confidence limit'
      ls='upper confidence limit';
```

```

*
*
*          PHARMACIA CNS R&D          9550082
*
*          APPENDIX No.: 12.1.11
*
*-----*
* PGM NAME: perul95
* CREATED: 15.02.94
* AIM : 95% exact confidence interval for a proportion
*-----*
* INPUT :
*
* _pop_ -> total number of patients
* _nr_ -> number of events
* % : pct=(_nr_/_pop_)*100
*
* OUTPUT :
* 195 -> % LOWER LIMIT
* u95 -> % UPPER LIMIT
*-----*

if pct = 0 then do;
    195=0;
    u95 = (1-exp(log(0.05)/_pop_) * 100;
end;

else
if pct = 100 then do;
    u95=100;
    195 = exp(log(0.05)/_pop_) * 100;
end;

else if pct ne . then do;
    li=pct/100; * lower limit ;
    ls=1; * upper limit ;

    do k=1 to 100;
        z=((ls - li) / 2) + li;
        a = probbnml(z,_pop_,_nr_);
        if .02501 > a > .02499 then leave;
        else
            if a > .02501 then li = z;
            else ls=z;
        end;
        u95 = z * 100;
        if k > 100 then put '**1** convergence was not attained in 100 '
            'iterations ' k= z= pct= ls= li= ;

    ls=pct/100; * limite superiore;
    li=0; * limite inferiore ;

    do k=1 to 100;
        z=((ls - li) / 2) + li;
        a = 1 - probbnml((1 - z),_pop_,(_pop_ - _nr_));
        if .97501 > a > .97499 then leave;
        else
            if a > .97501 then li = z;
            else ls=z;
        end;
        195 = z * 100;
        if k > 100 then put '**1** convergence was not attained in 100 '
            'iterations ' k= z= pct= ls= li= ;
    end;
end;

```

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```
*
*                               PHARMACIA CNS R&D                9550082      ;
*                               APPENDIX No.: 12.1.11            ;
*                               ;                                  ;
*-----*
* PGM NAME: bartlett                                           *
* CREATED: 18.10.95                                           *
* AIM   : Bartlett's test for the equality of variances        *
*-----*

proc sort data=last out=lbart;
  by cod_trt;

proc means data=lbart noprint;
  by cod_trt; * compute the within-group sample variance;
  var diffn;
  format cod_trt $ftrt.;
  output out=bartl n=num var=var;
run;

data _null_;
  set bartl end=fine;
  retain sumdf suminvdf sumlvadf sumdfvar n 0;

  * compute the pooled variance;
  n=_N;
  df=num-1;

  logvar=log10(var);
  logvardf=df*logvar;
  sumlvadf=sumlvadf+logvardf;

  sumdf=sumdf+df;

  invdf=1/df;
  suminvdf=suminvdf+invdf;

  dfvar=df*var;
  sumdfvar=sumdfvar+dfvar;

  logs=log10(sumdfvar/sumdf); * log(base10) (var. totale);

  if fine then do;
    m=log(10)*(sumdf*logs-sumlvadf);
    chidf=n-1;
    c=1+(1/(3*chidf))*(suminvdf-(1/sumdf));
    chi=m/c;
    output;
  end;
  p=1-probchi(chi,chidf);

  file print;
  if fine
    then put /// |
             /// |@69 "BARTLETT'S TEST RESULTS"
             /// |
             /@45 "CHI SQUARE = ' chi ' WITH ' chidf
                'DEGREES OF FREEDOM p= ' p;

run;
```

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Document 9550082

12.1.12 SELECTION OF STATISTICAL ANALYSIS OUTPUTS

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

733

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REBOXETINE - PROTOCOL 20124/015

Appendix No.: 12.1.12

SELECTION OF STATISTICAL ANALYSIS OUTPUTS

Efficacy analyses

Study end point : HAMD decrease

- ANOVA on baseline values for comparison between treatments
- ANOVA on decreases at last assessment according to the models:
HAMD decrease = treatment + sex + sex * treatment
HAMD decrease = treatment + diagnosis + treatment * diagnosis

The following analyses have been carried out on three sets of patients: all patients, severe and melancholic patients.

- Tables showing descriptive statistics (n, mean, standard deviation S.D.)
- Bartlett test for testing homogeneity of variances
- ANOVA according to the model : HAMD decrease = treatment
- one-side Dunnett's test for comparison between each active treatment and placebo

Response : 50% HAMD decrease

- Chi square test for the comparison of the frequency of responders in each active treatment Vs placebo group.
- Log-rank test on time to response (pairwise comparisons between each of the active treatments and placebo)

Remission : HAMD total score lower than or equal to 10

- Chi square test for the comparison of the number of remission cases in each active treatment and in placebo group

Analysis of Adverse events

- Log-rank test on the time to the first occurrence of either any event and selected signs-symptoms (pairwise comparisons between each of the active treatment and placebo)

9550082

1

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON AT BASELINE
General Linear Models Procedure
Class Level Information
Class Levels Values
CDD_TRT 3 INI PLC RBX
Number of observations in data set = 332

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

735

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

2

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON AT BASELINE

General Linear Models Procedure

Dependent Variable: RANO

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	2	20.72609800	10.36304900	0.41	0.6631
Error	329	8288.31908272	25.19245922		
Corrected Total	331	8309.04518072			

R-Square	C.V.	Root MSE
0.002494	18.45992	5.01920902

Source	DF	Type I SS	Mean Square	F Value	Pr > F
CDD_TRT	2	20.72609800	10.36304900	0.41	0.6631
Source	DF	Type III SS	Mean Square	F Value	Pr > F
CDD_TRT	2	20.72609800	10.36304900	0.41	0.6631

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

1

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COD_TRT	3	IMI PLC RBX
SEX	2	F M

Number of observations in data set = 332

9550082

737

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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KEROMETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variable: DIFFN

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	836.37894136	167.27578827	1.65	0.1464
Error	326	33056.09093815	101.39905196		
Corrected Total	331	33892.46987952			

R-Square	C.V.	Root MSE	DIFFN Mean
0.024677	78.36717	10.06970963	12.84939759

Source	DF	Type I SS	Mean Square	F Value	Pr > F
COD_TRT	2	410.83482628	205.41741314	2.03	0.1335
SEX	1	0.58760159	0.58760159	0.01	0.9394
COD_TRT*SEX	2	424.95651349	212.47825675	2.10	0.1247

Source	DF	Type III SS	Mean Square	F Value	Pr > F
COD_TRT	2	406.14884366	203.07442183	2.00	0.1366
SEX	1	0.41871360	0.41871360	0.00	0.9488
COD_TRT*SEX	2	424.95651349	212.47825675	2.10	0.1247

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

1

PHARMACIA CMS RED
REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COD_TRT	3	IMI PLC RBX
DSMIII	2	296.2 296.3

Number of observations in data set = 331

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2

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REDUXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variable: DIFFN

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	590.33749693	118.06749939	1.15	0.3313
Error	325	33223.58395322	102.22641216		
Corrected Total	330	33813.92145015			

R-Square 0.017458
 C.V. 78.52286
 Root MSE 10.11070780
 DIFFN Mean 12.87613293

Source	DF	Type I SS	Mean Square	F Value	Pr > F
COD_TRT	2	428.70122083	214.35061042	2.10	0.1245
DSMIII	1	51.10710833	51.10710833	0.50	0.4800
COD_TRT*DSMIII	2	110.52916777	55.26458388	0.54	0.5829
Source	DF	Type III SS <th>Mean Square</th> <th>F Value</th> <th>Pr > F</th>	Mean Square	F Value	Pr > F
COD_TRT	2	317.48636835	158.74318418	1.55	0.2132
DSMIII	1	50.42113892	50.42113892	0.49	0.4830
COD_TRT*DSMIII	2	110.52916777	55.26458388	0.54	0.5829

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PREMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

TABLE OF COD_TRT BY RESP

COD_TRT(treatment code)	RESP		Total
	0	1	
Frequency Expected Percent			
Row Pct			
Col Pct			
PLC	53 49.222 23.98	58 61.778 26.24	111 50.23
RBX	45 48.778 20.36	65 61.222 29.41	110 49.77
Total	98 44.34	123 55.66	221 100.00

STATISTICS FOR TABLE OF COD_TRT BY RESP

Statistic	DF	Value	Prob
Chi-Square	1	1.047	0.306
Likelihood Ratio Chi-Square	1	1.048	0.306
Continuity Adj. Chi-Square	1	0.788	0.375
Nantal-Haenszel Chi-Square	1	1.042	0.307
Fisher's Exact Test (Left)			0.877
(Right)			0.187
(2-Tail)			0.344
Phi Coefficient		0.069	
Contingency Coefficient		0.069	
Cramer's V		0.069	

Sample Size = 221

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

TABLE OF COD_TRT BY RESP

COD_TRT(treatment code)		RESP		Total
Frequency	Expected Percent	0	1	
IMI		42 47.5 18.92	69 63.5 31.08	111 111 50.00
PLC		53 47.5 23.87	58 63.5 26.13	111 111 50.00
Total		95 42.75	127 57.21	222 100.00

STATISTICS FOR TABLE OF COD_TRT BY RESP

Statistic	DF	Value	Prob
Chi-Square	1	2.226	0.136
Likelihood Ratio Chi-Square	1	2.230	0.135
Continuity Adj. Chi-Square	1	1.840	0.175
Nantal-Haenszel Chi-Square	1	2.216	0.137
Fisher's Exact Test (Left)			0.087
(Right)			0.948
(2-Tail)			0.175
Phi Coefficient		-0.100	
Contingency Coefficient		0.100	
Cramer's V		-0.100	

Sample Size = 222

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

TABLE OF COD_TRT BY REM

COD_TRT(treatment code)		Frequency		Total
Expected	Percent	0	1	
PLC		71	40	111
		67.303	48.697	
		32.13	18.10	50.23
		63.96	36.04	
		52.99	45.98	
RBX		63	47	110
		66.697	43.303	
		28.51	21.27	49.77
		57.27	42.73	
		47.01	54.02	
Total		134	87	221
		60.63	39.37	100.00

STATISTICS FOR TABLE OF COD_TRT BY REM

Statistic	DF	Value	Prob
Chi-Square	1	1.036	0.309
Likelihood Ratio Chi-Square	1	1.037	0.308
Continuity Adj. Chi-Square	1	0.775	0.379
Nominal-Residual Chi-Square	1	1.032	0.310
Fisher's Exact Test (Left)			0.876
Fisher's Exact Test (Right)			0.189
Fisher's Exact Test (2-Tail)			0.337
Phi Coefficient		0.068	
Contingency Coefficient		0.068	
Cramer's V		0.068	

Sample Size = 221

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REMOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

TABLE OF COD_TRT BY REM

COD_TRT(treatment code)		REM		Total
Frequency	Expected	0	1	Total
Percent	Row Pct	Col Pct		
IMI	55 24.77	56 25.23	48 50.45	111 50.00
PLC	71 31.98	40 18.02	48 36.04	111 50.00
Total	126 56.76	96 43.24	222 100.00	

STATISTICS FOR TABLE OF COD_TRT BY REM

Statistic	DF	Value	Prob
Chi-Square	1	4.698	0.030
Likelihood Ratio Chi-Square	1	4.716	0.030
Continuity Adj. Chi-Square	1	4.129	0.042
Nantal-Haenszel Chi-Square	1	4.677	0.031
Fisher's Exact Test (Left)			0.021
(Right)			0.989
(2-Tail)			0.042
Phi Coefficient		-0.145	
Contingency Coefficient		0.144	
Cramer's V		-0.145	
Sample Size = 222			

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12
EFFICACY: KAPLAN / MEIER ANALYSIS - TIME TO ONSET OF RESPONSE (50 X HAMILTON DECREASE)
FAILURE DISTRIBUTION FUNCTION

Treatment	Days of treatment	Events	Withdrawals (t-1 -- t)	At risk (t -- t+1)	FDF C.I.		FDF		FDF C.I.			
					lower	95%	estimate	upper	95%			
Imipramine	0	111	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000		
	7	107	0.00000	0.00909	0.00909	0.02683	0.00909	0.02683	0.00909	0.02683		
	8	98	0.00441	0.03687	0.03687	0.07234	0.03687	0.07234	0.03687	0.07234		
	14	89	0.03280	0.08756	0.08756	0.14233	0.08756	0.14233	0.08756	0.14233		
	15	81	0.08757	0.15933	0.15933	0.23109	0.15933	0.23109	0.15933	0.23109		
	16	1	80	0.09680	0.16971	0.16971	0.24341	0.16971	0.24341	0.16971	0.24341	
	21	8	66	0.16826	0.25487	0.25487	0.34147	0.25487	0.34147	0.25487	0.34147	
	22	13	53	0.30189	0.40163	0.40163	0.50137	0.40163	0.50137	0.40163	0.50137	
	23	1	51	0.31264	0.41292	0.41292	0.51321	0.41292	0.51321	0.41292	0.51321	
	25	1	50	0.32361	0.42444	0.42444	0.52526	0.42444	0.52526	0.42444	0.52526	
	26	1	49	0.33465	0.43595	0.43595	0.53725	0.43595	0.53725	0.43595	0.53725	
	28	4	44	0.37940	0.48199	0.48199	0.58458	0.48199	0.58458	0.48199	0.58458	
	29	7	37	0.46156	0.56440	0.56440	0.66724	0.56440	0.66724	0.56440	0.66724	
	31	1	35	0.47356	0.57618	0.57618	0.67879	0.57618	0.67879	0.57618	0.67879	
	33	1	33	0.48589	0.58828	0.58828	0.69068	0.58828	0.69068	0.58828	0.69068	
	36	5	27	0.55024	0.65067	0.65067	0.75109	0.65067	0.75109	0.65067	0.75109	
	41	1	25	0.56415	0.66410	0.66410	0.76405	0.66410	0.76405	0.66410	0.76405	
	42	4	6	0.62100	0.71785	0.71785	0.81462	0.71785	0.81462	0.71785	0.81462	
	43	3	3	0.73609	0.83892	0.83892	0.96175	0.83892	0.96175	0.83892	0.96175	
	44	1	2	0.79473	0.90595	0.90595	1.00000	0.90595	1.00000	0.90595	1.00000	
	45	1	0	0.86730	0.95297	0.95297	1.00000	0.95297	1.00000	0.95297	1.00000	
	Placebo	0	111	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	
		8	103	0.00000	0.01869	0.01869	0.04435	0.01869	0.04435	0.01869	0.04435	
		12	1	100	0.06000	0.02841	0.02841	0.06010	0.02841	0.06010	0.02841	
		14	2	97	0.06691	0.04784	0.04784	0.08877	0.04784	0.08877	0.04784	
		15	5	91	0.03980	0.09692	0.09692	0.15404	0.09692	0.15404	0.09692	
		21	3	86	0.06244	0.12702	0.12702	0.19160	0.12702	0.19160	0.12702	
		22	11	73	0.15520	0.23868	0.23868	0.32216	0.23868	0.32216	0.23868	
		23	1	72	0.16431	0.24911	0.24911	0.33591	0.24911	0.33591	0.24911	
		28	6	62	0.22162	0.31347	0.31347	0.40532	0.31347	0.40532	0.31347	
		29	7	55	0.29319	0.39098	0.39098	0.48878	0.39098	0.48878	0.39098	
		31	1	53	0.30381	0.40226	0.40226	0.50071	0.40226	0.50071	0.40226	
		35	2	50	0.32524	0.42482	0.42482	0.52439	0.42482	0.52439	0.42482	
		36	4	46	0.36953	0.47083	0.47083	0.57214	0.47083	0.57214	0.47083	
		37	2	44	0.39205	0.49384	0.49384	0.59564	0.49384	0.59564	0.49384	
		42	4	14	0.43868	0.54092	0.54092	0.64317	0.54092	0.64317	0.54092	
		43	6	2	0.60510	0.73767	0.73767	0.87024	0.73767	0.87024	0.73767	
		45	1	0	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000
		Reboxetine	0	110	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
			8	3	103	0.00000	0.02850	0.02850	0.05987	0.02850	0.05987	0.02850
			13	1	99	0.00146	0.03783	0.03783	0.07419	0.03783	0.07419	0.03783
			14	7	91	0.04668	0.10586	0.10586	0.16504	0.10586	0.16504	0.10586
			15	6	83	0.09316	0.16481	0.16481	0.23647	0.16481	0.23647	0.16481
			21	4	77	0.12706	0.20556	0.20556	0.28405	0.20556	0.28405	0.20556
			22	12	64	0.23699	0.32937	0.32937	0.42174	0.32937	0.42174	0.32937
28			3	57	0.26727	0.36235	0.36235	0.45742	0.36235	0.45742	0.36235	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 EFFICACY: KAPLAN / MEIER ANALYSIS - TIME TO ONSET OF RESPONSE (50 % HAMILTON DECREASE)
 FAILURE DISTRIBUTION FUNCTION

Treatment	Days of treatment	Events	Withdrawals (t-1 -- t)	At risk (t -- t+1)	FDF C.I.		FDF estimate	FDF C.I.	
					lower	upper		95%	95%
Reboxetine	29	7	1	49	0.34112	0.44066	0.44066	0.54019	0.54019
	34	3	1	45	0.37475	0.47561	0.47561	0.57648	0.57648
	35	5	0	40	0.43211	0.53388	0.53388	0.63565	0.63565
	36	7	0	33	0.51514	0.61545	0.61545	0.71576	0.71576
	42	4	23	6	0.56406	0.66206	0.66206	0.76006	0.76006
	43	2	3	1	0.63147	0.77471	0.77471	0.91794	0.91794
	44	1	0	0	1.00000	1.00000	1.00000	1.00000	1.00000

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PHARMACIA CNS R&D
 RENDYXETINE - PROTOCOL 2012A/015
 APPENDIX No.: 12.1.12
 EFFICACY: KAPLAN / MEIER ANALYSIS - TIME TO ONSET OF RESPONSE (50 % HAMILTON DECREASE)

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	111	69	42	37.8378
RBX	110	65	45	40.9091
Total	221	134	87	39.3665

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics		
COD_TRT	Log-Rank	Wilcoxon
IMI	5.5996	806.00
RBX	-5.5996	-806.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	29.2737	-29.2737
RBX	-29.2737	29.2737

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	572340	-572340
RBX	-572340	572340

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	1.0711	1	0.3007
Wilcoxon	1.4351	1	0.2867
-2Log(LR)	0.7401	1	0.3894

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PHARMACIA CNS R&D

REBOVENINE - PROTOCOL 20124/015
APPENDIX No. 1: 12.1.12

EFFICACY: KAPLAN / MEIER ANALYSIS - TIME TO ONSET OF RESPONSE (50 % HAMILTON DECREASE)

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
PLC	111	58	53	47.7477
RBX	110	65	45	40.9091
Total	221	123	98	44.3439

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-9.0868	-1292.0
RBX	9.0868	1292.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	27.1537	-27.1537
RBX	-27.1537	27.1537

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	578912	-578912
RBX	-578912	578912

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	3.0408	1	0.0812
Wilcoxon	2.8635	1	0.0895
-2Log(LR)	1.0819	1	0.2983

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 EFFICACY: KAPLAN / MEIER ANALYSIS - TIME TO ONSET OF RESPONSE (50 % HAMILTON DECREASE)

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
INI	111	69	42	37.8378
PLC	111	58	53	47.7477
Total	222	127	95	42.7928

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Milcoxon
INI	14.488	2094.0
PLC	-14.488	-2094.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	INI	PLC
INI	27.2814	-27.2814
PLC	-27.2814	27.2814

Covariance Matrix for the Milcoxon Statistics

COD_TRT	INI	PLC
INI	549491	-549491
PLC	-549491	549491

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	7.6935	1	0.0055
Milcoxon	7.9796	1	0.0047
-2Log(LR)	3.5183	1	0.0607

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX NO.:12.1.12

HAMILTON DEPRESSION RATING SCALE
 SUMMARY STATISTICS AT LAST ASSESSMENT

TREATMENT	HAMILTON TOTAL SCORE		BASELINE	LAST ASSESSMENT	DECREASE
	N	MEAN			
Imipramine	N		111	111	111
	MEAN		26.93	13.15	13.77
	S.D.		4.67	9.91	10.23
Placebo	N		111	111	111
	MEAN		27.12	15.83	11.29
	S.D.		5.30	9.58	10.06
Reboxetine	N		110	110	110
	MEAN		27.53	14.04	13.49
	S.D.		5.07	9.22	9.97

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

BARTLETT'S TEST RESULTS

CHI SQUARE = 0.0752492524 WITH 2 DEGREES OF FREEDOM P= 0.9630787198

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COD_TRT	3	INI PLC RBX

Number of observations in data set = 332

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variable: DIFFN		DF	Sum of Squares	Mean Square	F Value	Pr > F
Source						
Model		2	410.83482628	205.41741314	2.02	0.1345
Error		329	33481.63505324	101.76788770		
Corrected Total		331	33892.46987952			
R-Square			C.V.	Root MSE		DIFFN Mean
		0.012122	78.50957	10.08600712		12.86939759
Source	DF	Type I SS	Mean Square	F Value	Pr > F	
COD_TRT	2	410.83482628	205.41741314	2.02	0.1345	
Source	DF	Type III SS	Mean Square	F Value	Pr > F	
COD_TRT	2	410.83482628	205.41741314	2.02	0.1345	

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dunnett's One-tailed T tests for variable: DIFFN

NOTE: This tests controls the type I experimentwise error for comparisons of all treatments against a control.

Alpha= 0.05 Confidence= 0.95 df= 329 MSE= 101.7679
Critical Value of Dunnett's T= 1.923

Comparisons significant at the 0.05 level are indicated by '***'.

COD_TRT Comparison	Simultaneous	
	Lower Confidence Limit	Upper Confidence Limit
IMI - PLC	-0.117	2.486
RBX - PLC	-0.407	2.203
		5.090
		4.812

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4

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

BARTLETT'S TEST RESULTS

CHI SQUARE = 0.6228624414 WITH 2 DEGREES OF FREEDOM P= 0.6627010995

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COD_TRT	3	IMI PLC RBX

Number of observations in data set = 227

NOTE: Due to missing values, only 226 observations can be used in this analysis.

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PHARMACIA CNS 882

REBOXETINE - PROTOCOL 20124/015

APPENDIX No.: 12.1.12

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variable: DIFFN							
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F		
Model	2	528.4964936	264.24821968	2.37	0.0957		
Error	223	24852.49471109	111.44616462				
Corrected Total	225	25380.99115044					
R-Square		C.V.	Root MSE				DIFFN Mean
0.020623		76.91290	10.55680655				13.72566372
		Type I SS	Mean Square	F Value	Pr > F		
Source	DF						
COD_TRT	2	528.4964936	264.24821968	2.37	0.0957		
Source	DF	Type III SS	Mean Square	F Value	Pr > F		
COD_TRT	2	528.4964936	264.24821968	2.37	0.0957		

14
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16

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dunnett's One-tailed T tests for variable: DIFFN

NOTE: This tests controls the type I experimentwise error for comparisons of all treatments against a control.

Alpha= 0.05 Confidence= 0.95 df= 223 MSE= 111.4462
Critical Value of Dunnett's T= 1.921

Comparisons significant at the 0.05 level are indicated by '***'.

COD_TRT Comparison	Simultaneous	
	Lower Confidence Limit	Upper Confidence Limit
INI - PLC	0.048	3.380
RBX - PLC	-0.107	3.255
		6.711 ***
		6.617

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PHARMACIA CNS R8D
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX NO.: 12.1.12
 HAMILTON DEPRESSION RATING SCALE
 DESCRIPTIVE STATISTICS ON LAST ASSESSMENT
 MELANCHOLIC PATIENTS

TOTAL SCORE HAMILTON		BASELINE	LAST ASSESS.	DECREASE
MELANCHOLIC	TREATMENT			
NO	Imipramine	N	53	53
		MEAN	25.45	12.75
	S.D.	2.86	8.25	
	Placebo	N	60	60
		MEAN	26.15	14.32
	S.D.	5.37	9.20	
YES	Reboxetine	N	46	46
		MEAN	24.98	16.33
	S.D.	2.78	9.60	
	Imipramine	N	44	44
		MEAN	28.98	15.23
	S.D.	6.08	11.88	
Placebo	N	41	41	
	MEAN	28.85	18.76	
S.D.	5.34	10.12		
Reboxetine	N	51	51	
	MEAN	29.78	12.14	
S.D.	5.81	8.81		

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4

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

MELANCHOLIC PATIENTS
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

BARTLETT'S TEST RESULTS

CHI SQUARE = 4.0885015361 WITH 2 DEGREES OF FREEDOM P= 0.1294771621

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12
MELANCHOLIC PATIENTS
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE
General Linear Models Procedure
Class Level Information
Class Levels Values
COD_TRT 3 IMI PLC RBX
Number of observations in data set = 140

NOTE: Due to missing values, only 136 observations can be used in this analysis.

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PEARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

MELANCHOLIC PATIENTS
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variable: DIFFN							
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F		
Model	2	1303.83877331	651.91938666	5.52	0.0050		
Error	133	15693.50681492	117.99629184				
Corrected Total	135	16997.34558824					
R-Square		C. V.	Root MSE			DIFFN Mean	
0.076708		76.98358	10.86260981			14.11029412	
		Type I SS	Mean Square	F Value	Pr > F		
Source	DF						
COD_TRT	2	1303.83877331	651.91938666	5.52	0.0050		
Source	DF	Type III SS	Mean Square	F Value	Pr > F		
COD_TRT	2	1303.83877331	651.91938666	5.52	0.0050		

763

PHARMACIA CNS R&D
 REROGENTINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 MELANCHOLIC PATIENTS
 ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dunnett's One-tailed T tests for variable: DIFFN

NOTE: This tests controls the type I experimentwise error for comparisons of all treatments against a control.

Alpha= 0.05 Confidence= 0.95 df= 133 MSE= 117.9963
 Critical Value of Dunnett's T= 1.927

Comparisons significant at the 0.05 level are indicated by '***'.

COD_TRT Comparison	Simultaneous Confidence Limit		Difference Between Means		Simultaneous Upper Confidence Limit	
	Lower	Upper	Lower	Upper	Lower	Upper
RFX - PLC	3.159		7.549		11.940	***
IMI - PLC	-0.891		3.652		8.196	

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REBOXETINE - PROTOCOL 20124/15

APPENDIX NO. 12.1.12
HAMILTON DECREASE AT LAST ASSESSMENT

BETWEEN TREATMENT DIFFERENCE AND 95% CONFIDENCE INTERVAL

POPULATION	MEAN REBOXETINE	MEAN IMIPRAMINE	DIFFERENCE CAMPION-STANDARD	LOWER LIMIT	UPPER LIMIT
TOTAL	13.49	13.77	-0.28	-2.94991	2.38991
ONLY MELANCHOLIC	17.65	13.75	3.90	-0.52088	8.32088
ONLY SEVERE	14.68	14.80	-0.12	-3.44132	3.20132

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATMENT

The LIFESTEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	81	34	29.5652
RBX	112	71	41	36.6071
Total	227	152	75	33.0396

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	7.1329	867.00
RBX	-7.1329	-867.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	34.4317	-34.4317
RBX	-34.4317	34.4317

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	922000	-922000
RBX	-922000	922000

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	1.4777	1	0.2241
Wilcoxon	0.8153	1	0.3666
-2Log(LR)	4.2204	1	0.0399

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATMENT

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	X Censored
PLC	112	58	54	48.2143
RBX	112	71	41	36.6071
Total	224	129	95	42.4107

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-10.748	-2100.0
RBX	10.748	2100.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	30.2177	-30.2177
RBX	-30.2177	30.2177

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	833970	-833970
RBX	-833970	833970

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	3.6228	1	0.0506
Wilcoxon	5.2680	1	0.0215
-2Log(LR)	4.2412	1	0.0395

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012A/015
 APPENDIX No.: 12.1.12
CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATMENT

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	ZCensored
IMI	115	81	34	29.5652
PLC	112	58	54	48.2143
Total	227	139	88	38.7665

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	18.534	3209.0
PLC	-18.534	-3209.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	31.7491	-31.7491
PLC	-31.7491	31.7491

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	874020	-874020
PLC	-874020	874020

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	10.8192	1	0.0010
Wilcoxon	11.7820	1	0.0006
-2Log(LR)	16.7170	1	0.0001

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20324/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	5	110	95.6522
RBX	112	11	101	90.1786
Total	227	16	211	92.9515

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	-2.9943	-619.00
RBX	2.9943	619.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	3.97647	-3.97647
RBX	-3.97647	3.97647

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	172461	-172461
RBX	-172461	172461

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	2.2547	1	0.1332
Wilcoxon	2.2217	1	0.1361
-2Log(LR)	2.0745	1	0.1498

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	Zensored
PLC	112	10	102	91.0714
RBX	112	11	101	90.1786
Total	224	21	203	90.6250

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-0.43291	-62.000
RBX	0.43291	62.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	5.21181	-5.21181
RBX	-5.21181	5.21181

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	227727	-227727
RBX	-227727	227727

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0360	1	0.8496
Wilcoxon	0.0169	1	0.8966
-2Log(LR)	0.0420	1	0.8377

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PHARMACIA CNS R&D
 RESOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	Zensored
IMI	115	5	110	95.6522
PLC	112	10	102	91.0714
Total	227	15	212	93.3921

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	-2.5921	-569.00
PLC	2.5921	569.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	3.73221	-3.73221
PLC	-3.73221	3.73221

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	167625	-167625
PLC	-167625	167625

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	1.8003	1	0.1797
Wilcoxon	1.9315	1	0.1646
-2Log(LR)	1.5345	1	0.2154

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING ASTHMA / FATIGUE

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	6	109	94.7826
RBX	112	4	108	96.4286
Total	227	10	217	95.5947

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	1.0510	158.00
RBX	-1.0510	-158.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	2.49813	-2.49813
RBX	-2.49813	2.49813

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	99457.0	-99457.0
RBX	-99457.0	99457.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.4422	1	0.5061
Wilcoxon	0.2510	1	0.6164
-2Log(LR)	0.5101	1	0.4751

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 RESOMETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING ASTHENIA / FATIGUE

The LIFEEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
PLC	112	4	108	96.4286
RBX	112	4	108	96.4286
Total	224	8	216	96.4286

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-0.01200	-14.000
RBX	0.01200	14.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	1.99269	-1.99269
RBX	-1.99269	1.99269

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	86299.5	-86299.5
RBX	-86299.5	86299.5

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0001	1	0.9932
Wilcoxon	0.0023	1	0.9620
-2Log(LR)	0.0002	1	0.9898

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING ASTHENIA / FATIGUE

The LIFE TEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	6	109	94.7826
PLC	112	4	108	96.4286
Total	227	10	217	95.5947

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	1.0706	177.00
PLC	-1.0706	-177.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	2.49639	-2.49639
PLC	-2.49639	2.49639

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	95294.1	-95294.1
PLC	-95294.1	95294.1

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.4591	1	0.4980
Wilcoxon	0.5288	1	0.5664
-2Log(LR)	0.4900	1	0.4839

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING BLURRED VISION

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	ZCensored
IMI	115	10	105	91.3043
RBX	112	6	106	94.6429
Total	227	16	211	92.9515

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	2.1554	400.00
RBX	-2.1554	-400.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	3.98514	-3.98514
RBX	-3.98514	3.98514

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	159695	-159695
RBX	-159695	159695

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	1.1657	1	0.2803
Wilcoxon	1.0019	1	0.3168
-2Log(LR)	1.3236	1	0.2500

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 EBONEXINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING BLURRED VISION

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
PLC	112	3	109	97.3214
RBX	112	6	106	94.6429
Total	224	9	215	95.9821

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-1.5169	-310.00
RBX	1.5169	310.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	2.24505	-2.24505
RBX	-2.24505	2.24505

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	96243.0	-96243.0
RBX	-96243.0	96243.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	1.0249	1	0.3144
Wilcoxon	0.9985	1	0.3177
-2Log(LR)	1.0520	1	0.3050

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING BLURRED VISION

The LIFEEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	10	105	91.3043
PLC	112	3	109	97.3214
Total	227	13	214	94.2731

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	3.6482	704.00
PLC	-3.6482	-704.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	3.23396	-3.23396
PLC	-3.23396	3.23396

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	128703	-128703
PLC	-128703	128703

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	4.1156	1	0.0425
Wilcoxon	3.8509	1	0.0497
-2Log(LR)	4.5851	1	0.0323

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING CONSTIPATION

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	Xensored
IMI	115	18	97	84.3478
RBX	112	17	95	84.8214
Total	227	35	192	84.5815

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	0.67680	12.000
RBX	-0.67680	-12.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	8.66579	-8.66579
RBX	-8.66579	8.66579

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	325343	-325343
RBX	-325343	325343

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.0529	1	0.8182
Wilcoxon	0.0004	1	0.9832
-2Log(LR)	0.1362	1	0.7121

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING CONSTIPATION

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
PLC	112	6	106	94.6429
RBX	112	17	95	84.8214
Total	224	23	201	89.7321

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-5.7862	-1202.0
RBX	5.7862	1202.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	5.71740	-5.71740
RBX	-5.71740	5.71740

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	231472	-231472
RBX	-231472	231472

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	5.8558	1	0.0155
Wilcoxon	6.2418	1	0.0125
-2Lag(LR)	6.3040	1	0.0120

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RESOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING CONSTIPATION

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	18	97	84.3478
PLC	112	6	106	94.6429
Total	227	24	203	89.4273

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	6.5712	1259.0
PLC	-6.5712	-1259.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	5.95786	-5.95786
PLC	-5.95786	5.95786

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	221931	-221931
PLC	-221931	221931

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	7.2476	1	0.0071
Wilcoxon	7.1422	1	0.0075
-2Log(LR)	8.0710	1	0.0045

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING HEADACHE / MIGRAINE

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	9	106	92.1739
RBX	112	15	97	86.6071
Total	227	24	203	89.4273

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	-3.2290	-742.00
RBX	3.2290	742.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	5.94381	-5.94381
RBX	-5.94381	5.94381

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	250240	-250240
RBX	-250240	250240

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	1.7542	1	0.1853
Wilcoxon	2.2001	1	0.1380
-2Log(LR)	1.5160	1	0.2182

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING HEADACHE / MIGRAINE

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRY	Total	Failed	Censored	%Censored
PLC	112	9	103	91.9643
RBX	112	15	97	86.6071
Total	224	24	200	89.2857

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRY	Log-Rank	Milcoxon
PLC	-3.2596	-731.00
RBX	3.2596	731.00

Covariance Matrix for the Log-Rank Statistics

COD_TRY	PLC	RBX
PLC	5.93844	-5.93844
RBX	-5.93844	5.93844

Covariance Matrix for the Milcoxon Statistics

COD_TRY	PLC	RBX
PLC	246895	-246895
RBX	-246895	246895

Test of Equality over Strata

Test	Chi-Square	DF	Pt >
Log-Rank	1.7892	1	0.1810
Milcoxon	2.1643	1	0.1442
-2Log(LR)	1.8208	1	0.1772

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 REBDEXITINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING HEADACHE / MIGRAINE

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	X Censored
IMI	115	9	106	92.1739
PLC	112	9	103	91.9643
Total	227	18	209	92.0705

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Milcoxon
IMI	0.10095	22.000
PLC	-0.10095	-22.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	4.46200	-4.46200
PLC	-4.46200	4.46200

Covariance Matrix for the Milcoxon Statistics

COD_TRT	IMI	PLC
IMI	178720	-178720
PLC	-178720	178720

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.0023	1	0.9619
Milcoxon	0.0027	1	0.9585
-2Log(LR)	0.0106	1	0.9181

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING HYPOTENSION AND RELATED SYMPTOMS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	20	95	82.6087
RBX	112	10	102	91.0714
Total	227	30	197	86.7841

Testing Homogeneity of Survival Curves over Strata
 Time Variable: DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	5.5611	1111.0
RBX	-5.5611	-1111.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	7.42875	-7.42875
RBX	-7.42875	7.42875

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	291279	-291279
RBX	-291279	291279

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	4.1630	1	0.0413
Wilcoxon	4.2376	1	0.0395
-2Log(LR)	4.8504	1	0.0276

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING HYPOTENSION AND RELATED SYMPTOMS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
PLC	112	6	106	94.6429
RBX	112	10	102	91.0714
Total	224	16	208	92.8571

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-2.0059	-418.00
RBX	2.0059	418.00

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Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	3.99752	-3.99752
RBX	-3.99752	3.99752

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	158295	-158295
RBX	-158295	158295

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	1.0066	1	0.3157
Wilcoxon	1.1038	1	0.2934
-2Log(LR)	1.0607	1	0.3031

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 REMOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING HYPOTENSION AND RELATED SYMPTOMS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	20	95	82.6087
PLC	112	6	106	94.6429
Total	227	26	201	88.5463

Testing Homogeneity of Survival Curves over Strata
 Time Variable: DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	7.5732	1536.0
PLC	-7.5732	-1536.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	6.44061	-6.44061
PLC	-6.44061	6.44061

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	250363	-250363
PLC	-250363	250363

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	8.9049	1	0.0028
Wilcoxon	9.4235	1	0.0021
-2Log(LR)	10.1118	1	0.0015

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING INSOMNIA

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	8	107	93.0435
RBX	112	12	100	89.2857
Total	227	20	207	91.1894

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	-1.9857	-410.00
RBX	1.9857	410.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	4.97007	-4.97007
RBX	-4.97007	4.97007

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	204710	-204710
RBX	-204710	204710

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.7933	1	0.3731
Wilcoxon	0.8212	1	0.3648
-2Log(LR)	0.6973	1	0.4037

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REBOVETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING INSOMNIA

The LIFEESTI Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
PLC	112	4	108	96.4286
RBX	112	12	100	89.2857
Total	224	16	208	92.8571

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-4.0739	-829.00
RBX	4.0739	829.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	3.98941	-3.98941
RBX	-3.98941	3.98941

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	166779	-166779
RBX	-166779	166779

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	4.1602	1	0.0414
Wilcoxon	4.1207	1	0.0424
-2Log(LR)	4.4791	1	0.0343

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 RENOVEXTINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING INSOMNIA

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	X Censored
IMI	115	8	107	93.0435
PLC	112	4	108	96.4286
Total	227	12	215	94.7137

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	2.0504	407.00
PLC	-2.0504	-407.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	2.98753	-2.98753
PLC	-2.98753	2.98753

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	124378	-124378
PLC	-124378	124378

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	1.4072	1	0.2355
Wilcoxon	1.3318	1	0.2485
-2Log(LR)	1.6274	1	0.2021

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REBOXYLINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING MOUTH DRY

The LIFEEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	49	66	57.3913
RBX	112	28	84	75.0000
Total	227	77	150	66.0793

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	12.896	2335.0
RBX	-12.896	-2335.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	18.4688	-18.4688
RBX	-18.4688	18.4688

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	642568	-642568
RBX	-642568	642568

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	9.0046	1	0.0027
Wilcoxon	8.4851	1	0.0036
-2Log(LR)	19.8606	1	0.0002

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REBOMETINE - PROTOCOL 2024/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING MOUTH DRY

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
PLC	112	14	98	87.5000
RBX	112	28	84	75.0000
Total	224	42	182	81.2500

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Milcoxon
PLC	-7.6558	-1534.0
RBX	7.6558	1534.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	10.3357	-10.3357
RBX	-10.3357	10.3357

Covariance Matrix for the Milcoxon Statistics

COD_TRT	PLC	RBX
PLC	400308	-400308
RBX	-400308	400308

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	5.6707	1	0.0173
Milcoxon	5.8784	1	0.0153
-2Log(LR)	6.2222	1	0.0126

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REBOMETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING MOUTH DRY

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	X Censored
IMI	115	49	66	57.3913
PLC	112	14	98	87.5000
Total	227	63	164	72.2467

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	20.396	3628.0
PLC	-20.396	-3628.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	15.1032	-15.1032
PLC	-15.1032	15.1032

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	545229	-545229
PLC	-545229	545229

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	27.5434	1	0.0001
Wilcoxon	26.8760	1	0.0001
-2Log(LR)	37.0287	1	0.0001

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 REBOMETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING NAUSEA AND RELATED SYMPTOMS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	17	98	85.2174
RBX	112	10	102	91.0714
Total	227	27	200	88.1057

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Milcoxon
IMI	3.7482	709.00
RBX	-3.7482	-709.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	6.69458	-6.69458
RBX	-6.69458	6.69458

Covariance Matrix for the Milcoxon Statistics

COD_TRT	IMI	RBX
IMI	267469	-267469
RBX	-267469	267469

Test of Equality over Strata

Test	Chi-Square	DF	Chi-Square	Pr >
Log-Rank	2.0986	1	0.1474	
Milcoxon	1.8794	1	0.1704	
-2Log(LR)	2.5167	1	0.1126	

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 REBOVETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING NAUSEA AND RELATED SYMPTOMS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
PLC	112	10	102	91.0714
RBX	112	10	102	91.0714
Total	224	20	204	91.0714

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-0.01046	-37.000
RBX	0.01046	37.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	4.97236	-4.97236
RBX	-4.97236	4.97236

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	201385	-201385
RBX	-201385	201385

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.0000	1	0.9963
Wilcoxon	0.0068	1	0.9943
-2Log(LR)	0.0000	1	0.9977

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING NAUSEA AND RELATED SYMPTOMS

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	ZCensored
IMI	115	17	98	85.2174
PLC	112	10	102	91.0714
Total	227	27	200	88.1057

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	3.8406	779.00
PLC	-3.8406	-779.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	6.70973	-6.70973
PLC	-6.70973	6.70973

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	260328	-260328
PLC	-260328	260328

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	2.4983	1	0.1182
Wilcoxon	2.3311	1	0.1268
-2Log(LR)	2.5273	1	0.1119

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 REBOMEXINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING PARAESTHESIA

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	6	109	94.7826
RBX	112	2	110	98.2143
Total	227	8	219	96.4758

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	2.0017	412.00
RBX	-2.0017	-412.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	1.99221	-1.99221
RBX	-1.99221	1.99221

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	92923.1	-92923.1
RBX	-92923.1	92923.1

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	2.0112	1	0.1561
Wilcoxon	4.8267	1	0.1765
-2Log(LR)	2.5049	1	0.1135

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING PARAESTHESIA

The LIFEEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
PLC	112	2	110	98.2143
RBX	112	2	110	98.2143
Total	224	4	220	98.2143

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	0.00685	-10.000
RBX	-0.00685	10.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	0.999974	-.999974
RBX	-.999974	0.999974

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	46435.0	-46435.0
RBX	-46435.0	46435.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0000	1	0.9945
Wilcoxon	0.0022	1	0.9650
-2Log(LR)	0.0003	1	0.9859

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING PARAESTHESIA

The LIFEEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	6	109	94.7826
PLC	112	2	110	98.2143
Total	227	8	219	96.4758

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	2.0267	435.00
PLC	-2.0267	-435.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	1.99649	-1.99649
PLC	-1.99649	1.99649

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	89246.0	-89246.0
PLC	-89246.0	89246.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	2.0573	1	0.1515
Wilcoxon	2.1203	1	0.1454
-2Log(LR)	2.4280	1	0.1192

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REBOVETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING SOMNOLENCE

The LIFEEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	Xensored
IMI	115	6	109	94.7826
RBX	112	1	111	99.1071
Total	227	7	220	96.9163

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	2.5159	578.00
RBX	-2.5159	-578.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	1.74458	-1.74458
RBX	-1.74458	1.74458

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	83505.0	-83505.0
RBX	-83505.0	83505.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	3.6284	1	0.0568
Wilcoxon	4.0008	1	0.0455
-2Log(LR)	4.5473	1	0.0330

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RENOXYTINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING SOMNOLENCE

The LIFEEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	X Censored
PLC	112	9	103	91.9643
REX	112	1	111	99.4071
Total	224	10	214	95.5357

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	4.4343	816.00
REX	-4.1343	-816.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	REX
PLC	2.49240	-2.49240
REX	-2.49240	2.49240

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	REX
PLC	97918.0	-97918.0
REX	-97918.0	97918.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	6.8579	1	0.0088
Wilcoxon	6.8001	1	0.0091
-2Log(LR)	7.8786	1	0.0050

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING SOMNOLENCE

The LIFEEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	6	109	94.7826
PLC	112	9	103	91.9643
Total	227	15	212	93.3921

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	-1.4550	-183.00
PLC	1.4550	183.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	3.72606	-3.72606
PLC	-3.72606	3.72606

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	154057	-154057
PLC	-154057	154057

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.5682	1	0.4510
Wilcoxon	0.2174	1	0.6410
-2Log(LR)	0.4657	1	0.4950

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING SWEATING INCREASED

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	22	93	80.8696
RBX	112	14	98	87.5000
Total	227	36	191	84.1410

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics			
COD_TRT	Log-Rank	Wilcoxon	
IMI	4.3832	845.00	
RBX	-4.3832	-845.00	

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	8.90132	-8.90132
RBX	-8.90132	8.90132

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	356121	-356121
RBX	-356121	356121

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	2.1584	1	0.1418
Wilcoxon	2.0050	1	0.1568
-2Log(LR)	2.7966	1	0.0969

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REBOVETIME - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING SWEATING INCREASED

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	Xensored
PLC	112	3	109	97.3214
RBX	112	14	98	87.5000
Total	224	17	207	92.4107

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Milcoxon
PLC	-5.6256	-1164.0
RBX	5.6256	1164.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	4.22166	-4.22166
RBX	-4.22166	4.22166

Covariance Matrix for the Milcoxon Statistics

COD_TRT	PLC	RBX
PLC	183570	-183570
RBX	-183570	183570

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	7.4965	1	0.0062
Milcoxon	7.3808	1	0.0066
-2Log(LR)	8.4722	1	0.0036

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING SWEATING INCREASED

The LIFEEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	22	93	80.8696
PLC	112	3	109	97.3214
Total	227	25	202	88.9868

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	9.9524	1990.0
PLC	-9.9524	-1990.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	6.19730	-6.19730
PLC	-6.19730	6.19730

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	256040	-256040
PLC	-256040	256040

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	15.9829	1	0.0001
Wilcoxon	15.4667	1	0.0001
-2Log(LR)	19.8038	1	0.0001

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING TACHICARDIA

The LIFEEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	4	111	96.5217
RBX	112	3	109	97.3214
Total	227	7	220	96.9163

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Milcoxon
IMI	0.51767	100.00
RBX	-0.51767	-100.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	1.74871	-1.74871
RBX	-1.74871	1.74871

Covariance Matrix for the Milcoxon Statistics

COD_TRT	IMI	RBX
IMI	78840.0	-78840.0
RBX	-78840.0	78840.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.1532	1	0.6955
Milcoxon	0.1268	1	0.7217
-2Log(LR)	0.2750	1	0.6029

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING TACHYCARDIA

The LIFEEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
PLC	112	0	112	100.0000
REX	112	3	109	97.3214
Total	224	3	221	98.6607

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-1.5003	-322.00
REX	1.5003	322.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	REX
PLC	0.749989	-.749989
REX	-.749989	0.749989

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	REX
PLC	34654.0	-34654.0
REX	-34654.0	34654.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	3.0010	1	0.0832
Wilcoxon	2.9920	1	0.0837
-2Log(LR)*	4.1735	1	0.0411

* some strata had no events

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 REBOMETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING TACHICARDIA

The LIFEEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	4	111	96.5217
PLC	112	0	112	100.0000
Total	227	4	223	98.2379

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	2.0196	424.00
PLC	-2.0196	-424.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	0.999114	-0.999114
PLC	-0.999114	0.999114

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	44292.0	-44292.0
PLC	-44292.0	44292.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	4.0824	1	0.0433
Wilcoxon	4.8589	1	0.0269
-2Log(LR)*	5.8869	1	0.0158

* some strata had no events

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING TREMOR

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	20	95	82.6087
RBX	112	6	106	94.6429
Total	227	26	201	88.5463

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	7.4724	1397.0
RBX	-7.4724	-1397.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	6.43315	-6.43315
RBX	-6.43315	6.43315

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	252826	-252826
RBX	-252826	252826

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	8.6796	1	0.0032
Wilcoxon	7.7192	1	0.0055
-2Log(LR)	10.1769	1	0.0014

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING TRENOR

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
PLC	112	5	107	95.5357
RBX	112	6	106	94.6429
Total	224	11	213	95.0893

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-0.48628	-103.00
RBX	0.48628	103.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	2.74085	-2.74085
RBX	-2.74085	2.74085

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	120685	-120685
RBX	-120685	120685

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.0863	1	0.7690
Wilcoxon	0.0879	1	0.7669
-2Log(LR)	0.0966	1	0.7559

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING TRENOR

The LIFEEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	20	95	82.6087
PLC	112	5	107	95.5357
Total	227	25	202	88.9568

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	7.9547	1497.0
PLC	-7.9547	-1497.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	6.19357	-6.19357
PLC	-6.19357	6.19357

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	242835	-242835
PLC	-242835	242835

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	10.2165	1	0.0014
Wilcoxon	9.2285	1	0.0024
-2Log(LR)	12.0972	1	0.0005

PHARMACIA CNS R&D
 REBONETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING URINARY HESITANCY / RETENTION

The LIFE TEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
IMI	115	1	114	99.1304
RBX	112	6	106	94.6429
Total	227	7	220	96.9163

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	-2.5235	-516.00
RBX	2.5235	516.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	1.74478	-1.74478
RBX	-1.74478	1.74478

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	77460.6	-77460.6
RBX	-77460.6	77460.6

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	3.6499	1	0.0561
Wilcoxon	3.4373	1	0.0637
-2Log(LR)	3.8314	1	0.0509

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING URINARY HESITANCY / RETENTION

The LIFEEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
PLC	112	2	110	98.2143
RBX	112	6	106	94.6429
Total	224	8	216	96.4286

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-1.9947	-594.00
RBX	1.9947	594.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	1.99744	-1.99744
RBX	-1.99744	1.99744

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	88520.0	-88520.0
RBX	-88520.0	88520.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	1.9920	1	0.1581
Wilcoxon	1.7537	1	0.1854
-2Log(LR)	2.1572	1	0.1419

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 REBOXETINE - PROTOCOL 20124/015
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING URINARY HESITANCY / RETENTION

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	1	114	99.1304
PLC	112	2	110	98.2143
Total	227	3	224	98.6784

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	-0.53584	-123.00
PLC	0.53584	123.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	0.749526	-.749526
PLC	-.749526	0.749526

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	37613.0	-37613.0
PLC	-37613.0	37613.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.3831	1	0.5360
Wilcoxon	0.4022	1	0.5259
-2Log(LR)	0.2988	1	0.5847

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING VERTIGO

The LIFEEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	7	108	93.9130
RBX	112	5	107	95.5357
Total	227	12	215	94.7137

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	0.98121	187.00
RBX	-0.98121	-187.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RBX
IMI	2.98684	-2.98684
RBX	-2.98684	2.98684

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RBX
IMI	136524	-136524
RBX	-136524	136524

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.3223	1	0.5702
Wilcoxon	0.2561	1	0.6128
-2Log(LR)	0.4965	1	0.4810

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REBOXYTINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING VERTIGO

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	X Censored
PLC	112	0	112	100.0000
RBX	112	5	107	95.5357
Total	224	5	219	97.7679

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-2.5119	-546.00
RBX	2.5119	546.00

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Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	1.24768	-1.24768
RBX	-1.24768	1.24768

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	59018.5	-59018.5
RBX	-59018.5	59018.5

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	5.0571	1	0.0245
Wilcoxon	5.0512	1	0.0246
-2Log(LR)*	6.9990	1	0.0082

* some strata had no events

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REBOXETINE - PROTOCOL 20124/015
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING VERTIGO

The LIFEEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	115	7	108	93.9130
PLC	112	0	112	100.0000
Total	227	7	220	96.9163

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	3.5194	745.00
PLC	-3.5194	-745.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	PLC
IMI	1.74145	-1.74145
PLC	-1.74145	1.74145

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	PLC
IMI	78760.5	-78760.5
PLC	-78760.5	78760.5

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	7.1125	1	0.0077
Wilcoxon	7.0470	1	0.0079
-2Log(LR)*	10.3214	1	0.0013

* some strata had no events

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12.2 Patient Information

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Document 9550082

12.2.1 SERIOUS ADVERSE EVENTS - CASE HISTORIES

Case summaries of serious adverse events reported on reference treatments.

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Document 9550082

CLINICAL REPORT

CASE SUMMARY OF EVENT	AU 0055
PROTOCOL N°	20124/015
PT. N°	11
SEX	F
AGE AT ENTRY	30
EXPERIMENTAL TREATMENT	Imipramine
DAILY DOSE	100 mg
TREATMENT PERIOD	10 October 1991 - 13 October 1991
AFTER DAYS	2
ADE (DATE OF THE EVENT)	POSTURAL HYPOTENSION, DIZZINESS AND FALLING UNCONSCIOUS (11 October 1991)
DISCONTINUED	Yes
COURSE	RECOVERED WITH SEQUELAE
RELEVANT HISTORY	SEE BASELINE CONDITIONS
RELEVANT BASELINE CONDIT.	MAJOR DEPRESSIVE DISORDER, MARFAN'S SYNDROME
PREVIOUS ANTIDEPRESSIVE TREATMENTS	TRIMIPRAMINE, FLUOXETINE
RELEVANT EVENTS	NO
CONCOMITANT MEDICATIONS	TEMAZEPAM

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Document 9550082

CLINICAL REPORT (continued)

CASE SUMMARY OF EVENT	AU 0101
PROTOCOL N°	20124/015
PT. N°	20
SEX	F
AGE AT ENTRY	59
EXPERIMENTAL TREATMENT	Imipramine
DAILY DOSE	100 mg
TREATMENT PERIOD	29 April 1992 - 09 June 1992
AFTER DAYS	1
ADE (DATE OF THE EVENT)	ATTENTION SEEKING OVERDOSE OF OXAZAPAM AND LACERATION OF WRIST (30 April 92)
DISCONTINUED	No
COURSE	RECOVERED
RELEVANT HISTORY	SEE BASELINE CONDITIONS
RELEVANT BASELINE CONDIT.	MAJOR DEPRESSIVE DISORDER
PREVIOUS ANTIDEPRESSIVE TREATMENTS	VENLAFAXINE
RELEVANT EVENTS	NO
CONCOMITANT MEDICATIONS	NONE

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CLINICAL REPORT (continued)

CASE SUMMARY OF EVENT	IT
PROTOCOL N°	20124/015
PT. N°	213
SEX	M
AGE AT ENTRY	59
EXPERIMENTAL TREATMENT	Imipramine
DAILY DOSE	100 mg
TREATMENT PERIOD	22 November 1991 - 24 November 1991
AFTER DAYS	3
ADE (DATE OF THE EVENT)	SUICIDE (25 November 1991)
DISCONTINUED	
COURSE	
RELEVANT HISTORY	SEE BASELINE CONDITIONS
RELEVANT BASELINE CONDIT.	MAJOR DEPRESSIVE DISORDER
PREVIOUS ANTIDEPRESSIVE TREATMENTS	CLOMIPRAMINE
RELEVANT EVENTS	NO
CONCOMITANT MEDICATIONS	NONE

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Document 9550082

CLINICAL REPORT (continued)

CASE SUMMARY OF EVENT	CA
PROTOCOL N°	20124/015
PT. N°	375
SEX	M
AGE AT ENTRY	47
EXPERIMENTAL TREATMENT	Imipramine
DAILY DOSE	100 mg
TREATMENT PERIOD	17 June 1992 - 18 June 1992
AFTER DAYS	2
ADE (DATE OF THE EVENT)	ATTEMPTED SUICIDE (18 June 1992)
DISCONTINUED	Yes
COURSE	UNDER TREATMENT
RELEVANT HISTORY	CANCER OF COLON (OPERATED), VIRAL PERICARDITIS
RELEVANT BASELINE CONDIT.	MAJOR DEPRESSIVE DISORDER
PREVIOUS ANTIDEPRESSIVE TREATMENTS	IMIPRAMINE
RELEVANT EVENTS	NO
CONCOMITANT MEDICATIONS	CHLORAL HYDRATE, ACETAMINOPHEN, CLONAZEPAM, FLURAZEPAM

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Document 9550082

CLINICAL REPORT (continued)

CASE SUMMARY OF EVENT	FR 0093
PROTOCOL N°	20124/015
PT. N°	176
SEX	F
AGE AT ENTRY	31
EXPERIMENTAL TREATMENT	Placebo
DAILY DOSE	0
TREATMENT PERIOD	14 March 1993 - 08 April 1992
AFTER DAYS	26
ADE (DATE OF THE EVENT)	ATTEMPTED SUICIDE (08 April 1992)
DISCONTINUED	Yes
COURSE	UNDER TREATMENT
RELEVANT HISTORY	SEE BASELINE CONDITIONS
RELEVANT BASELINE CONDIT.	MAJOR DEPRESSIVE DISORDER
PREVIOUS ANTIDEPRESSIVE TREATMENTS	NO
RELEVANT EVENTS	NO
CONCOMITANT MEDICATIONS	CHLORAL HYDRATE

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Document 9550082

CLINICAL REPORT (continued)

CASE SUMMARY OF EVENT	FR 0123
PROTOCOL N°	20124/015
PT. N°	179
SEX	F
AGE AT ENTRY	43
EXPERIMENTAL TREATMENT	Placebo
DAILY DOSE	0
TREATMENT PERIOD	11 September 1992 - 29 September 1992
AFTER DAYS	19
ADE (DATE OF THE EVENT)	ATTEMPTED SUICIDE (29 September 1992)
DISCONTINUED	Yes
COURSE	RECOVERED
RELEVANT HISTORY	SEE BASELINE CONDITIONS
RELEVANT BASELINE CONDIT.	MAJOR DEPRESSIVE DISORDER
PREVIOUS ANTIDEPRESSIVE TREATMENTS	FLUOXETINE
RELEVANT EVENTS	NO
CONCOMITANT MEDICATIONS	CHLORAL HYDRATE

12.2.2 INDIVIDUAL DATA LISTINGS

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	In-out patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)
1	1	Imipramine	MJS	OUT		Female	35	54.0	165.0	Caucasian	296.3	22.0
	2	Reboxetine	HK	OUT		Male	49	75.0	170.0	Caucasian	296.3	20.0
	3	Imipramine	WP	OUT		Male	41	77.0	172.0	Caucasian	296.3	22.0
	4	Placebo	KJ	IN	02/06/91	Male	35	93.0	190.0	Caucasian	296.2	24.0
	5	Reboxetine	MC	OUT		Female	37	67.0	160.0	Caucasian	296.3	24.0
	6	Placebo	MC	OUT		Female	36	54.0	166.0	Caucasian	296.3	29.0
	7	Reboxetine	TC	OUT		Female	19	46.0	158.0	Caucasian	296.2	28.0
	8	Placebo	AT	OUT		Male	64.0	174.0	174.0	Caucasian	296.3	28.0
	9	Reboxetine	ME	OUT		Female	33	64.0	166.0	Caucasian	296.3	22.0
	10	Placebo	JB	OUT		Female	35	77.0	160.0	Caucasian	296.3	29.0
2/1	11	Imipramine	NK	OUT		Female	30	58.0	173.0	Caucasian	296.3	28.0
	12	Imipramine	JF	OUT		Female	30	62.0	173.0	Caucasian	296.3	30.0
	412	Reboxetine	PG	OUT		Female	41	76.0	173.0	Caucasian	296.3	30.0
	413	Placebo	RJ	OUT		Male	51	72.0	181.0	Caucasian	296.3	29.0
	414	Imipramine	JC	IN	17/01/92	Female	47	67.0	168.0	Caucasian	296.3	24.0
	415	Imipramine	TM	OUT		Male	40	67.0	170.0	Caucasian	296.3	28.0
	416	Reboxetine	TH	OUT		Female	41	66.0	168.0	Caucasian	296.3	26.0
	421	Reboxetine	EK	OUT		Female	57	77.0	168.0	Caucasian	296.3	25.0
	422	Imipramine	NJ	OUT		Male	44	61.0	161.0	Caucasian	296.2	28.0
	49	Placebo	PIN	IN	13/05/91	Female	53	60.0	151.0	Caucasian	296.3	22.0
50	Reboxetine	MAG	IN	21/12/91	Female	43	50.0	152.0	Caucasian	296.3	29.0	
51	Imipramine	CES	IN	24/01/92	Female	38	68.0	168.0	Caucasian	296.2	25.0	
2/2	43	Imipramine	VAL	OUT		Female	26	61.0	175.0	Caucasian	296.3	30.0
	44	Imipramine	STE	OUT		Female	20	62.0	165.0	Caucasian	296.3	30.0
	45	Reboxetine	BER	OUT		Female	26	59.6	160.0	Caucasian	296.3	30.0
	46	Placebo	GEO	OUT		Female	43	63.0	165.0	Caucasian	296.3	30.0
2/3	47	Placebo	FA	OUT		Female	35	59.0	164.0	Caucasian	296.3	30.0
	48	Reboxetine	FAY	OUT		Female	31	64.0	158.0	Caucasian	296.2	30.0
	36/A	Imipramine	ROU	OUT		Male	53	99.0	170.0	Caucasian	296.3	29.0
	37	Reboxetine	DNF	OUT		Female	46	43.0	161.0	Caucasian	296.3	25.0
2/4	38	Placebo	PEJ	OUT		Male	45	94.0	174.0	Caucasian	296.2	26.0
	39	Imipramine	PHI	OUT		Female	52	60.0	162.0	Caucasian	296.3	28.0
	40	Reboxetine	SG	IN	17/10/91	Female	59	38.0	162.0	Caucasian	296.3	27.0
	41	Placebo	ND	OUT		Male	25	63.0	169.0	Caucasian	296.3	30.0
42	Imipramine	JD	IN	04/05/92	Female	40	78.0	155.0	Caucasian	296.3	25.0	
2/4	31	Placebo	CHA	OUT		Male	35	75.0	170.0	Caucasian	296.2	26.0
	32	Reboxetine	MAL	OUT		Male	59	86.0	175.0	Caucasian	296.2	30.0

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
300.4=Depression, Bipolar

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	In-out patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)
2/4	33	Imipramine	LDM	OUT		Male	38	80.0	180.0	Caucasian	296.2	25.0
	34	Placebo	DES	OUT		Female	55	42.0	155.0	Caucasian	296.3	20.0
	35	Reboxetine	ADB	OUT		Female	64	65.0	160.0	Caucasian	296.2	26.0
	36	Imipramine	XIB	OUT		Female	57	45.0	140.0	Caucasian	296.3	20.0
2/5	73	Placebo	DND	IN	27/01/92	Male	45	73.0	173.0	Caucasian	296.3	26.0
	76	Reboxetine	GAU	IN	15/04/92	Male	52	65.0	194.0	Caucasian	296.2	28.0
	76	Imipramine	THO	IN	03/09/92	Male	50	71.0	181.0	Caucasian	296.3	29.0
	77	Imipramine	REV	IN	09/09/92	Female	32	45.0	178.0	Caucasian	296.2	30.0
78	Placebo	BRE	IN	03/06/92	Male	36	77.0	178.0	Caucasian	296.3	28.0	
	Reboxetine	ASS	IN	29/09/92	Female	51	57.0	161.0	Caucasian	296.3	27.0	
2/6	55	Reboxetine	THE	IN	12/06/92	Female	57	55.0	162.0	Caucasian	296.2	30.0
	56	Reboxetine	DEG	IN	12/06/92	Female	59	64.0	157.0	Caucasian	296.2	29.0
	57	Imipramine	CON	OUT		Female	57	60.0	155.0	Caucasian	296.3	29.0
	58	Placebo	ROU	IN	17/05/92	Female	59	55.0	158.0	Caucasian	296.3	29.0
	59	Placebo	FOU	IN	26/05/92	Male	33	70.0	175.0	Caucasian	296.2	30.0
	60	Imipramine	MAR	IN	11/05/92	Female	38	47.0	155.0	Caucasian	296.3	29.0
3/1	61	Imipramine	THI	OUT		Male	22	79.0	173.0	Caucasian	296.2	28.0
	62	Imipramine	TOU	IN	12/04/91	Female	24	60.0	165.0	Caucasian	296.3	30.0
	63	Placebo	SAC	IN	10/03/91	Male	43	70.0	165.0	Caucasian	296.2	30.0
	64	Placebo	PF	OUT		Female	57	63.0	163.0	Caucasian	296.3	27.0
	65	Reboxetine	AMA	IN	11/09/91	Male	62	70.0	168.0	Caucasian	296.2	29.0
	66	Reboxetine	RF	OUT		Male	50	90.0	170.0	Caucasian	296.2	30.0
	739	Imipramine	H B	OUT		Male	31	61.0	168.0	Caucasian	296.3	30.0
	140	Placebo	BH	OUT		Male	56	67.0	182.0	Caucasian	296.3	30.0
	141	Placebo	K M	OUT		Female	40	56.0	162.0	Caucasian	296.3	30.0
	142	Imipramine	KAR	IN	14/11/91	Female	20	50.0	152.0	Caucasian	296.2	30.0
	143	Reboxetine	R H	OUT		Female	44	48.0	152.0	Caucasian	296.2	27.0
	451	Reboxetine	MD	OUT		Female	26	42.0	169.0	Caucasian	296.2	29.0
452	Placebo	G D	OUT		Female	57	76.0	163.0	Caucasian	296.3	29.0	
453	Imipramine	TL	OUT		Male	44	70.0	170.0	Caucasian	296.2	29.0	
454	Reboxetine	EG	OUT		Female	55	72.0	155.0	Caucasian	296.3	26.0	
455	Placebo	BN	OUT		Male	56	77.0	172.0	Caucasian	296.3	29.0	
456	Imipramine	GH	OUT		Female	47	58.0	164.0	Caucasian	296.3	28.0	
3/2	65/A	Reboxetine	REN	IN	23/01/91	Female	21	56.0	169.0	Caucasian	296.3	30.0

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-out Patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)
3/3	67	Placebo	JND	IN	12/07/91	Male	38	61.0	168.0	Caucasian	296.3	25.0
	68	Reboxetine	MHO	IN	10/01/92	Male	45	80.0	180.0	Caucasian	296.3	25.0
	69	Placebo	AMA	IN	29/01/92	Male	34	60.0	173.0	Caucasian	296.3	26.0
	70	Imipramine	RDE	IN	08/04/92	Male	40	77.0	178.0	Caucasian	296.2	26.0
	71	Imipramine	SDU	IN	10/04/92	Female	26	57.0	170.0	Caucasian	296.3	30.0
72	Reboxetine	PDU	IN	20/07/92	Male	31	65.0	179.0	Caucasian	296.2	28.0	
3/4	78	Imipramine	BIA	IN	01/05/91	Female	45	50.0	157.0	Caucasian	296.3	22.0
	80	Imipramine	DUH	IN	31/05/91	Male	46	48.0	176.0	Caucasian	296.2	27.0
	81	Reboxetine	SUA	IN	16/05/91	Female	35	55.0	165.0	Caucasian	296.2	26.0
	82	Placebo	PER	IN	14/06/91	Male	49	71.0	162.0	Caucasian	296.2	29.0
	83	Placebo	FOU	OUT	14/06/91	Male	49	75.0	174.0	Caucasian	296.2	30.0
	84	Reboxetine	HOU	IN	07/10/91	Female	27	60.0	158.0	Caucasian	296.2	25.0
	85	Imipramine	NAR	IN	25/10/91	Female	45	54.0	160.0	Caucasian	296.3	30.0
	86	Imipramine	COU	OUT	10/10/91	Male	34	63.0	174.0	Caucasian	296.2	26.0
	87	Placebo	HAI	IN	05/12/91	Female	33	61.0	162.0	Caucasian	296.3	30.0
	88	Placebo	NOI	OUT	05/12/91	Male	53	76.0	168.0	Caucasian	296.2	28.0
	89	Reboxetine	ANN	OUT	05/12/91	Female	49	51.0	163.0	Caucasian	296.3	28.0
	90	Reboxetine	CDR	OUT	05/12/91	Male	47	72.0	174.0	Caucasian	296.2	28.0
∞ ∞ ∞	457	Placebo	PRD	IN	18/05/92	Female	48	63.0	167.0	Caucasian	296.3	30.0
	458	Reboxetine	LAU	OUT	18/05/92	Female	43	79.0	167.0	Caucasian	296.3	30.0
	459	Placebo	NGU	OUT	18/05/92	Female	57	41.0	158.0	Asian	296.3	30.0
	460	Reboxetine	CHA	OUT	18/05/92	Male	38	62.0	174.0	Caucasian	296.2	30.0
	461	Imipramine	BRA	OUT	18/05/92	Female	45	79.0	167.0	Caucasian	296.2	28.0
	462	Imipramine	VOU	OUT	18/05/92	Female	39	68.0	166.0	Caucasian	296.2	28.0
4/1	91	Imipramine	MAI	OUT	18/05/92	Female	36	67.0	165.0	Caucasian	296.2	29.0
	92	Reboxetine	ADE	OUT	18/05/92	Female	28	41.0	160.0	Caucasian	296.3	30.0
	93	Placebo	AUB	OUT	18/05/92	Male	18	71.0	179.0	Caucasian	296.2	28.0
	94	Placebo	MAI	OUT	18/05/92	Female	59	60.0	157.0	Caucasian	296.3	28.0
	95	Imipramine	CHA	OUT	18/05/92	Female	42	77.0	154.0	Caucasian	296.3	28.0
	96	Reboxetine	ABR	OUT	18/05/92	Female	52	79.0	157.0	Caucasian	296.3	29.0
	115	Reboxetine	CED	OUT	18/05/92	Female	55	76.0	148.0	Caucasian	296.3	30.0
	116	Imipramine	EST	OUT	18/05/92	Female	41	56.0	163.0	Caucasian	296.3	30.0
	117	Imipramine	EWA	OUT	18/05/92	Female	59	64.0	160.0	Caucasian	296.2	29.0
	118	Reboxetine	BAR	OUT	18/05/92	Female	43	84.0	161.0	Caucasian	296.2	29.0
	119	Placebo	RAY	OUT	18/05/92	Female	46	54.0	168.0	Caucasian	296.3	29.0
	128	Placebo	ZEL	OUT	18/05/92	Female	45	52.0	164.0	Caucasian	296.3	29.0
	145	Imipramine	LON	OUT	18/05/92	Female	45	62.0	163.0	Caucasian	296.3	29.0
	146	Placebo	BOU	OUT	18/05/92	Female	57	42.0	162.0	Caucasian	296.3	29.0
	147	Reboxetine	REC	OUT	18/05/92	Female	45	92.0	152.0	Caucasian	296.2	29.0
	148	Imipramine	ALC	OUT	18/05/92	Female	59	77.0	164.0	Caucasian	296.3	29.0
149	Reboxetine	LNU	OUT	18/05/92	Male	56	74.0	170.0	Caucasian	296.2	30.0	

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episodes
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

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PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20124/015
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-out Hospital patient	Date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)
4/1	150	Placebo	GIL	OUT		Male	52	82.0	169.0	Caucasian	296.3	29.0
4/2	93/A	Placebo	GRA	OUT		Male	48	100.0	178.0	Caucasian	296.3	23.0
	99/A	Placebo	GHE	OUT		Male	48	83.0	176.0	Caucasian	296.3	24.0
	104	Reboxetine	DUP	OUT		Male	57	82.0	178.0	Caucasian	296.3	24.0
4/3	97	Placebo	DEL	OUT		Male	42	62.0	173.0	Caucasian	296.3	28.0
	98	Reboxetine	PER	OUT		Female	53	53.0	159.0	Caucasian	296.3	28.0
	99	Placebo	LEH	OUT		Female	59	40.0	153.0	Caucasian	296.3	28.0
	100	Imipramine	ERR	OUT		Female	24	44.0	145.0	Caucasian	296.3	25.0
	101	Imipramine	PEL	OUT		Male	55	74.0	180.0	Caucasian	296.3	27.0
4/4	109	Reboxetine	DUC	OUT		Female	28	59.0	151.0	Caucasian	296.3	25.0
	110	Imipramine	DUP	IN	06/06/91	Male	64	66.5	158.0	Caucasian	296.3	28.0
	111	Imipramine	ROU	OUT		Male	45	66.0	169.0	Caucasian	296.3	30.0
	112	Placebo	ROT	IN		Male	23	65.0	174.0	Caucasian	296.3	30.0
	113	Reboxetine	NIC	IN	05/07/91	Male	23	96.6	184.0	Caucasian	296.3	29.0
	114	Placebo	ROT	OUT	25/08/91	Male	62	61.0	155.0	Caucasian	296.3	27.0
	175	Imipramine	DAN	IN	10/02/92	Female	48	50.0	157.0	Caucasian	296.3	29.0
	176	Placebo	HOR	IN	11/03/92	Female	31	50.0	160.0	Caucasian	296.3	27.0
	177	Imipramine	HEL	OUT		Female	55	59.0	155.0	Caucasian	296.3	25.0
	178	Reboxetine	JEF	IN	18/04/92	Female	35	71.0	171.0	Caucasian	296.3	26.0
	179	Placebo	JEG	IN	07/09/92	Female	43	65.5	158.0	Caucasian	296.3	30.0
	180	Reboxetine	ROU	IN	16/09/92	Male	40	69.0	173.0	Caucasian	296.3	30.0
5/1	127	Reboxetine	SUZ	IN	28/05/91	Male	34	84.0	179.0	Caucasian	296.3	30.0
	128	Reboxetine	FRD	IN	08/06/91	Female	33	54.0	159.0	Caucasian	296.3	29.0
	129	Placebo	BEA	IN	16/12/91	Male	19	55.0	163.0	Caucasian	296.3	30.0
	130	Placebo	THE	IN	24/02/92	Male	30	58.0	176.0	Caucasian	296.3	29.0
	131	Imipramine	GUT	IN	18/03/92	Female	43	81.0	155.0	Caucasian	296.3	27.0
	132	Imipramine	DE	IN	18/06/92	Male	38	83.0	170.0	Caucasian	296.2	30.0
5/2	121	Imipramine	ROU	OUT	19/12/91	Female	20	45.0	162.0	Caucasian	296.3	27.0
	125	Reboxetine	ROL	IN	24/01/91	Male	48	72.0	169.0	Caucasian	296.3	28.0
5/3	133	Placebo	MAR	IN	23/11/91	Male	55	72.0	172.0	Caucasian	296.3	30.0
	134	Reboxetine	HOL	IN	29/11/91	Female	31	47.0	147.0	Caucasian	296.3	26.0
	135	Imipramine	SOU	IN	05/01/92	Female	48	76.0	162.0	Caucasian	296.3	29.0
	136	Imipramine	POM	IN	18/02/92	Female	47	75.0	150.0	Caucasian	296.3	27.0

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
300.4=Dysrhythmia

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-out Hospital patient	Age (years)	Height (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)	
5/3	137	Reboxetine	MAG	IN	32	46.0	151.0	Caucasian	296.3	28.0	
	138	Placebo	PLU	IN	31	59.0	158.0	Caucasian	296.2	28.0	
6/1	151	Imipramine	LEC	OUT	63	55.0	172.0	Caucasian	296.2	29.0	
	152	Reboxetine	REA	OUT	56	57.0	172.0	Caucasian	296.3	29.0	
	153	Reboxetine	REZ	OUT	20	52.0	173.0	Caucasian	296.2	30.0	
	154	Imipramine	REK	OUT	26	52.0	173.0	Caucasian	296.2	30.0	
	155	Placebo	CHA	OUT	63	76.0	171.0	Caucasian	296.3	30.0	
	156	Placebo	VON	OUT	41	72.0	156.0	Caucasian	296.3	27.0	
6/2	157	Reboxetine	MAZ	OUT	43	61.0	176.0	Caucasian	296.3	29.0	
	158	Imipramine	KER	OUT	37	52.0	163.0	Caucasian	296.3	30.0	
	159	Imipramine	JEG	IN	46	89.0	178.0	Caucasian	296.3	29.0	
	160	Placebo	MEN	IN	35	89.0	179.0	Caucasian	296.2	30.0	
	161	Reboxetine	BRE	OUT	20	56.0	160.0	Caucasian	296.2	30.0	
	162	Placebo	MAR	IN	47	70.0	172.0	Caucasian	296.2	30.0	
	169	Imipramine	BUR	OUT	53	52.0	161.0	Caucasian	296.3	28.0	
	170	Placebo	LD	OUT	45	88.0	180.0	Caucasian	296.3	24.0	
	171	Imipramine	PAG	OUT	54	52.0	161.0	Caucasian	296.2	27.0	
	172	Reboxetine	PAJ	OUT	72	52.0	147.0	Caucasian	296.2	27.0	
	173	Placebo	RAO	OUT	44	75.0	181.0	Caucasian	296.2	27.0	
	174	Reboxetine	COL	OUT	55	77.0	175.0	Caucasian	296.3	28.0	
	6/3	163	Reboxetine	FEV	OUT	37	63.0	178.0	Caucasian	296.3	24.0
		164	Imipramine	BRO	OUT	29	74.0	178.0	Caucasian	296.3	28.0
165		Imipramine	BAS	OUT	54	49.0	159.0	Caucasian	296.3	29.0	
166		Reboxetine	CLE	OUT	40	60.0	167.0	Caucasian	296.3	26.0	
167		Placebo	JUS	OUT	33	55.0	162.0	Caucasian	296.3	30.0	
168		Placebo	DUC	OUT	34	80.0	161.0	Caucasian	296.3	26.0	
505		Imipramine	CHA	OUT	41	56.0	158.0	Caucasian	296.3	26.0	
507		Placebo	HEI	OUT	48	89.0	174.0	Caucasian	296.3	26.0	
508		Imipramine	NOU	OUT	34	57.0	160.0	Caucasian	296.3	30.0	
509		Reboxetine	GRE	OUT	52	60.0	150.0	Caucasian	296.3	26.0	
510		Placebo	EAZ	OUT	27	52.0	164.0	Caucasian	296.3	30.0	
511		Reboxetine	LAU	OUT	20	55.0	157.0	Caucasian	296.2	26.0	
512		Imipramine	LES	OUT	21	68.0	167.0	Caucasian	296.2	26.0	
515	Placebo	RAD	OUT	25	68.0	169.0	Asian	296.3	26.0		
7/02	181	Reboxetine	VH	OUT	36	85.0	182.0	Caucasian	296.2	29.0	
	182	Placebo	HLE	OUT	57	64.0	176.0	Caucasian	296.3	29.0	

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	In-out patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)	
7/02	183	Imipramine	HHE	OUT		Male	51	93.0	183.0	Caucasian	296.2	30.0	
	184	Imipramine	HT	OUT		Female	43	60.0	160.0	Caucasian	296.2	27.0	
	185	Reboxetine	HT	OUT		Male	59	73.0	172.0	Caucasian	296.2	30.0	
	186	Placebo	HRS	OUT		Male	36	67.0	170.0	Caucasian	296.2	30.0	
	535	Placebo	GR	OUT		Male	40	85.0	182.0	Caucasian	296.3	30.0	
	536	Reboxetine	KR	OUT		Female	32	80.0	172.0	Caucasian	296.2	27.0	
	7/03	187	Imipramine	HK	OUT		Female	49	77.0	165.0	Caucasian	296.2	26.0
		188	Placebo	HK	OUT		Male	38	71.0	175.0	Caucasian	296.2	26.0
		189	Placebo	HM	OUT		Male	50	86.0	174.0	Caucasian	296.3	27.0
		190	Reboxetine	JS	OUT		Male	43	80.0	178.0	Caucasian	296.2	29.0
191		Imipramine	AM	OUT		Female	43	85.0	185.0	Caucasian	296.2	27.0	
192		Reboxetine	AK	OUT		Female	43	85.0	178.0	Caucasian	296.2	27.0	
523		Reboxetine	DC	OUT		Female	35	52.0	146.0	Caucasian	296.3	26.0	
524		Placebo	DB	OUT		Female	26	52.0	152.0	Caucasian	296.2	26.0	
525		Placebo	CM	OUT		Female	35	91.0	160.0	Caucasian	296.3	25.0	
526		Reboxetine	MG	OUT		Female	57	97.0	171.0	Caucasian	296.3	25.0	
7/04	527	Imipramine	RE	OUT		Female	36	60.0	168.0	Caucasian	296.2	25.0	
	528	Imipramine	CR	OUT		Female	35	64.0	160.0	Caucasian	296.2	26.0	
	193	Placebo	SN	OUT		Female	64	61.0	163.0	Caucasian	296.2	29.0	
	194	Reboxetine	SC	OUT		Male	28	78.0	180.0	Caucasian	296.2	29.0	
	195	Placebo	HM	OUT		Female	60	67.0	162.0	Caucasian	296.2	28.0	
	196	Reboxetine	FH	OUT		Female	50	67.0	164.0	Caucasian	296.2	28.0	
	197	Imipramine	FJ	OUT		Male	30	79.0	180.0	Caucasian	296.2	28.0	
	198	Imipramine	KN	OUT		Female	55	61.0	164.0	Caucasian	296.2	28.0	
	199	Imipramine	LD	OUT		Female	55	78.0	180.0	Caucasian	296.2	27.0	
	200	Placebo	FB	OUT		Male	40	89.0	184.0	Caucasian	296.2	25.0	
7/05	201	Reboxetine	OH	OUT		Female	59	79.0	165.0	Caucasian	296.2	25.0	
	202	Reboxetine	EH	OUT		Male	38	96.0	179.0	Caucasian	296.2	26.0	
	203	Placebo	FA	OUT		Female	41	67.0	167.0	Caucasian	296.2	26.0	
	204	Imipramine	ZC	OUT		Female	58	82.0	165.0	Caucasian	296.2	26.0	
	205	Placebo	MS	OUT		Male	61	74.0	169.0	Caucasian	296.3	27.0	
	206	Imipramine	BR	OUT		Female	52	72.0	155.0	Caucasian	296.3	26.0	
	207	Imipramine	BR	OUT		Female	62	72.0	158.0	Caucasian	296.2	27.0	
	208	Reboxetine	EM	OUT		Male	42	75.0	174.0	Caucasian	296.3	28.0	
	209	Placebo	AM	OUT		Male	53	86.0	177.0	Caucasian	296.2	26.0	
	210	Reboxetine	GX	OUT		Male	64	76.0	170.0	Caucasian	296.2	25.0	
541	Reboxetine	HH	OUT		Female	59	74.0	168.0	Caucasian	296.3	25.0		
542	Imipramine	JN	OUT		Male	47	83.0	172.0	Caucasian	296.3	25.0		
543	Imipramine	UF	OUT		Male	50	98.0	185.0	Caucasian	296.3	28.0		

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
300.4=Bythymia

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Lasting No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	In-out Patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)
7/05	544	Placebo	JT	OUT		Female	56	72.0	170.0	Caucasian	296.3	26.0
	545	Reboxetine	MR	OUT		Male	55	74.0	168.0	Caucasian	296.3	26.0
7/07	529	Placebo	ND	OUT		Female	57	75.0	170.0	Caucasian	296.3	27.0
	530	Imipramine	NR	OUT		Female	53	73.0	163.0	Caucasian	296.3	29.0
8	211	Reboxetine	DUN	IN	07/05/91	Female	41	65.0	168.0	Caucasian	296.3	28.0
	212	Placebo	GR	IN	10/09/91	Female	65	76.5	162.0	Caucasian	296.3	26.0
	213	Imipramine	DS	OUT	21/11/91	Male	59	79.0	173.0	Caucasian	296.3	27.0
	214	Reboxetine	RUB	IN	19/11/91	Female	54	72.0	160.0	Caucasian	296.3	26.0
	215	Placebo	RIM	IN	14/02/92	Female	46	43.0	166.0	Caucasian	296.3	30.0
	216	Imipramine	LEP	OUT	26/03/92	Male	46	92.0	180.0	Caucasian	296.3	29.0
8	217	Reboxetine	LEO	IN	23/03/92	Female	41	62.8	167.0	Caucasian	296.3	29.0
	218	Reboxetine	SNS	OUT		Female	53	66.0	170.0	Caucasian	296.3	29.0
	219	Placebo	DID	OUT		Female	23	52.0	162.0	Caucasian	296.3	30.0
	220	Imipramine	CLA	IN	21/04/92	Female	38	56.5	163.0	Caucasian	296.3	30.0
	221	Imipramine	CEL	IN	24/04/92	Male	41	77.0	170.0	Caucasian	296.3	30.0
	222	Placebo	ROL	IN	20/04/92	Female	64	66.0	162.0	Caucasian	296.3	28.0
	223	Imipramine	MAA	IN	04/05/92	Female	57	54.0	166.0	Caucasian	296.3	30.0
	224	Placebo	VER	OUT		Female	25	56.0	164.0	Caucasian	296.3	30.0
	225	Placebo	BED	OUT		Male	20	68.0	170.0	Caucasian	296.3	29.0
	226	Reboxetine	GIC	OUT		Male	58	62.0	162.0	Caucasian	296.3	28.0
8/A	227	Reboxetine	PEH	OUT		Male	64	70.0	172.0	Caucasian	296.3	30.0
	228	Imipramine	SAR	OUT		Male	31	74.0	172.0	Caucasian	296.3	29.0
	229	Imipramine	COE	OUT		Female	55	66.0	162.0	Caucasian	296.3	28.0
	230	Reboxetine	MAG	OUT		Female	43	56.0	160.0	Caucasian	296.3	29.0
	231	Imipramine	STE	OUT		Male	46	88.0	180.0	Caucasian	296.3	30.0
	232	Reboxetine	SPA	OUT		Male	29	76.0	186.0	Caucasian	296.3	30.0
	233	Placebo	WPA	OUT		Female	52	70.0	164.0	Caucasian	296.3	30.0
	234	Placebo	FRH	OUT		Female	65	62.0	163.0	Caucasian	296.3	27.0
	235	Placebo	BM	OUT		Female	62	75.0	155.0	Caucasian	296.3	27.0
	236	Placebo	DN	OUT		Female	44	65.0	163.0	Caucasian	296.3	27.0
237	Reboxetine	DC	OUT		Female	57	63.0	163.0	Caucasian	296.3	26.0	
238	Reboxetine	GR	OUT		Female	52	62.0	164.0	Caucasian	296.3	27.0	
239	Imipramine	GG	OUT		Female	42	62.0	164.0	Caucasian	296.3	27.0	
240	Imipramine	LL	OUT		Female	46	66.0	163.0	Caucasian	296.3	26.0	

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episodes
300.4=Dysthymia

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8

PHARMACIA CMS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	In-out patient	Patient status In-out Hospital	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)	
8/A	553	Placebo	LM	OUT	Female	36	68.0	164.0	Caucasian	296.3	25.0	
	554	Reboxetine	PF	OUT	Male	60	64.0	160.0	Caucasian	296.3	27.0	
	555	Reboxetine	SC	OUT	Female	64	57.0	153.0	Caucasian	296.3	25.0	
556	Imipramine	PG	OUT	Male	43	64.0	164.0	Caucasian	296.3	25.0		
9	241	Placebo	MG	IN	Female	43	58.0	163.0	Caucasian	296.3	30.0	
	242	Reboxetine	RF	IN	Female	55	62.0	164.0	Caucasian	296.3	26.0	
	243	Reboxetine	RF	IN	Female	54	67.5	165.0	Caucasian	296.3	27.0	
	244	Imipramine	MC	IN	Female	56	69.0	158.0	Caucasian	296.3	30.0	
	245	Imipramine	MC	IN	Female	44	61.5	170.0	Caucasian	296.3	29.0	
	246	Placebo	MC	IN	Female	41	69.0	160.0	Caucasian	296.3	28.0	
	247	Placebo	VM	IN	Female	33	69.0	169.0	Caucasian	296.3	29.0	
	248	Placebo	TS	IN	Female	37	81.5	175.0	Caucasian	296.3	27.0	
	249	Reboxetine	RF	IN	Female	42	72.0	164.0	Caucasian	296.3	30.0	
	250	Imipramine	RF	IN	Female	51	52.0	158.0	Caucasian	296.5	27.0	
	251	Imipramine	LBS	IN	Female	22	61.0	173.0	Caucasian	296.2	28.0	
	252	Reboxetine	DSF	IN	Female	61	116.0	160.0	Caucasian	296.3	27.0	
	253	Reboxetine	PH	IN	Female	32	67.5	168.0	Caucasian	296.3	30.0	
	254	Imipramine	PL	IN	Female	54	71.5	160.0	Caucasian	296.3	26.0	
	255	Reboxetine	BM	IN	Female	24	76.0	158.0	Caucasian	296.2	26.0	
	256	Imipramine	BA	IN	Female	51	54.0	165.0	Caucasian	296.3	30.0	
	257	Placebo	TS	IN	Male	25	64.0	155.0	Caucasian	296.2	29.0	
	258	Placebo	AG	IN	Male	29	48.5	160.0	Caucasian	296.2	30.0	
	11	319	Placebo	PA	OUT	Male	45	74.0	175.0	Caucasian	296.2	30.0
		320	Imipramine	RZ	OUT	Male	34	74.0	163.0	IRANIAN	296.3	30.0
321		Placebo	EK	OUT	Male	45	65.0	165.0	Caucasian	296.3	29.0	
322		Reboxetine	JN	OUT	Female	57	73.0	170.0	Caucasian	296.3	28.0	
323		Reboxetine	LB	OUT	Male	36	65.0	178.0	Caucasian	296.2	30.0	
324		Imipramine	MC	OUT	Male	31	76.0	173.0	Caucasian	296.2	28.0	
325		Reboxetine	JFC	OUT	Male	58	85.0	185.0	Caucasian	296.2	29.0	
326		Placebo	CH	OUT	Male	55	75.0	168.0	Caucasian	296.3	30.0	
327		Imipramine	NA	OUT	Male	33	64.0	183.0	Caucasian	296.3	30.0	
328		Imipramine	SM	OUT	Female	29	60.0	168.0	Caucasian	296.3	29.0	
329		Placebo	LG	OUT	Female	40	86.0	160.0	Caucasian	296.3	30.0	
330		Reboxetine	JL	OUT	Male	36	69.0	160.0	Caucasian	296.2	29.0	
331		Imipramine	JK	OUT	Male	34	74.0	163.0	Caucasian	296.3	29.0	
332	Reboxetine	KE	OUT	Male	64	79.0	180.0	Caucasian	296.3	28.0		
333	Placebo	AL	OUT	Male	33	193.0	183.0	Caucasian	296.2	29.0		
334	Reboxetine	FT	OUT	Female	36	103.0	190.0	IRANIAN	296.2	29.0		
335	Placebo	EM	OUT	Male	38	109.0	193.0	Caucasian	296.3	30.0		
336	Imipramine	EM	OUT	Female	42	99.0	173.0	Caucasian	296.3	29.0		
337	Reboxetine	EM	OUT	Female	25	64.0	165.0	Caucasian	296.3	30.0		

(*) DIAGNOSIS: 296 2=Major Depressive Disorder, First Episode
296 3=Major Depressive Disorder, Multiple Episodes
296 5=Major Depressive Disorder, Bipolar
300 4=Dysrhythmia

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-out Hospital patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)	Mini-mental state exam. (total score)
11	338	Imipramine	GT	OUT		Male	29	75.0	183.0	Caucasian	296.2	30.0
12	367	Reboxetine	DSP	IN	11/12/91	Female	62	51.5	152.0	Caucasian	296.3	27.0
	368	Placebo	RJD	IN	16/12/91	Female	40	77.2	161.0	Caucasian	296.2	29.0
	369	Imipramine	SJD	IN	14/04/92	Female	50	70.4	165.0	Caucasian	296.3	29.0
	370	Placebo	DCB	IN	13/04/92	Male	50	99.0	170.0	Caucasian	296.3	26.0
	371	Imipramine	DCB	IN	13/04/92	Female	36	141.0	178.0	Caucasian	296.3	30.0
	372	Reboxetine	DRM	OUT	04/05/92	Male	52	71.0	172.0	Caucasian	296.3	28.0
	373	Reboxetine	RJP	IN	04/05/92	Female	34	71.0	145.0	Caucasian	296.3	30.0
	374	Placebo	NCT	IN	08/02/92	Female	34	71.0	145.0	Caucasian	296.3	28.0
	375	Imipramine	SIC	IN	05/06/92	Male	47	78.1	172.0	Caucasian	296.3	30.0
13	13	Placebo	EP	IN	03/04/91	Male	44	80.0	178.0	Caucasian	296.3	27.0
	14	Placebo	SMF	OUT		Male	28	78.0	180.0	SRI-LANKA	296.3	29.0
	15	Imipramine	CLB	IN	01/07/91	Female	29	80.7	164.0	Caucasian	296.3	30.0
	16	Imipramine	RD	OUT		Male	52	95.0	175.0	Caucasian	296.3	30.0
	17	Reboxetine	SC	OUT		Male	35	65.0	177.0	Caucasian	296.3	29.0
	18	Reboxetine	IZ	OUT		Male	51	82.5	175.0	Caucasian	296.3	28.0
	409	Reboxetine	BC	OUT		Male	61	68.0	177.0	Caucasian	296.3	30.0
	410	Placebo	JMT	OUT		Male	45	65.0	169.0	Caucasian	296.3	27.0
	411	Placebo	JMT	OUT	18/03/92	Female	40	47.0	158.0	Caucasian	296.3	27.0
	423	Imipramine	JJC	OUT		Male	52	87.2	179.0	Caucasian	296.3	30.0
14	19	Reboxetine	VB	IN	02/04/92	Female	52	89.0	161.0	Caucasian	296.3	26.0
	20	Imipramine	MR	IN	24/04/92	Female	59	85.0	179.0	Caucasian	296.3	30.0
	21	Imipramine	MD	IN	15/07/92	Female	59	83.0	160.0	Caucasian	296.3	23.0
15	25	Reboxetine	NN	OUT		Female	60	65.0	153.0	Caucasian	296.3	29.0
	26	Placebo	VJ	OUT		Male	36	80.0	165.0	Caucasian	296.3	30.0
	27	Imipramine	EB	OUT		Female	53	40.0	151.0	Caucasian	296.3	30.0
	28	Reboxetine	JB	OUT		Female	43	82.0	175.0	Caucasian	296.3	30.0
	29	Placebo	DC	IN	28/08/91	Male	47	87.0	170.0	Caucasian	296.2	28.0
	30	Imipramine	BH	OUT		Female	44	85.0	167.0	Caucasian	296.3	30.0
	402	Imipramine	JHB	IN	02/10/91	Female	44	61.0	135.0	Caucasian	296.2	30.0
	403	Reboxetine	BY	OUT		Female	42	67.0	162.0	Caucasian	296.2	30.0
	404	Placebo	BS	OUT		Female	49	77.5	163.0	Caucasian	296.2	30.0
	405	Imipramine	DS	OUT		Male	21	77.0	165.0	Caucasian	296.2	30.0
	407	Reboxetine	SC	IN	29/11/91	Female	30	52.5	141.0	Caucasian	296.3	30.0
	408	Reboxetine	SC	IN	08/01/92	Female	30	49.0	143.0	Caucasian	296.3	30.0
	418	Placebo	LM	OUT		Female	63	59.5	161.0	Caucasian	296.3	30.0
	419	Placebo	JH	OUT		Female	30	56.5	163.0	Caucasian	296.3	30.0

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episodes
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Unknown	History of mental disorder		Duration at the time of admission	Best characterized	Present episode		External stress
			Age of onset	No. of episodes last episode			Onset was	Onset was	
1	1		1	10 weeks	2 months and 5 days	Similar prev. cond.	Acute (< 2 weeks)	Absent	
	2		4	12 weeks	3 months	Similar prev. cond.	Acute (< 2 weeks)	Probably present	
	3		4	2 weeks	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	4		0	2 weeks	3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	5		1	5 months	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	6		7	8 months	1 month	Similar prev. cond.	Insidious (>= 3 months)	Absent	
	7	Yes	0	4 months	4 months	First occurrence	Insidious (>= 3 months)	Absent	
	8		1	4 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	9		1	12 weeks	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	10		3	2 years	20 days	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	11		3	20 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	12		1	2 months	10 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	13		1	7 weeks	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	14		4	3 years	3 months	Chronic condition	Insidious (>= 3 months)	Probably present	
	15		4	3 months	10 weeks	Chronic condition	Insidious (>= 3 months)	Probably present	
	16		1	8 weeks	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	17		1	6 months	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
18		1	3 months	3 months	First occurrence	Subacute (>= 2 weeks)	Definitely present		
2/1	49		1	8 weeks	8 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	50		4	3 months	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	51		2	1 month	1 month	Different prev. cond.	Subacute (>= 2 weeks)	Probably present	
	43		2	6 months	3 months	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	44		3	3 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
2/2	45		10	2 months	4 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
	46		2	3 months	1 month	Different prev. cond.	Subacute (>= 2 weeks)	Probably present	
	47		2	6 months	3 months	Chronic condition	Insidious (>= 3 months)	Probably present	
	48	Yes	2	6 months	2 months	Chronic condition	Insidious (>= 3 months)	Probably present	
	36/A		5	10 weeks	10 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	37		2	16 weeks	5 weeks	Chronic condition	Insidious (>= 3 months)	Probably present	
2/3	38		0	1 month and 21 days	1 month and 21 days	First occurrence	Insidious (>= 3 months)	Probably present	
	39		3	3 months	2 months	Chronic condition	Subacute (>= 2 weeks)	Definitely present	
	40		4	2 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	41		2	4 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	42		4	1 month	1 month and 15 days	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	31	Yes	2	months	2 months	Chronic condition	Subacute (>= 2 weeks)	Absent	
	32	Yes	1	month	1 month	Chronic condition	Insidious (>= 3 months)	Absent	
	33	Yes	4	weeks	4 weeks	Chronic condition	Insidious (>= 3 months)	Absent	
2/4	34	Yes	5	weeks	5 weeks	First occurrence	Acute (< 2 weeks)	Absent	
	35	Yes	1	month	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	36	Yes	64	1 month	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	37	Yes	64	1 month	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	38	Yes	64	1 month	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Unknown	History of mental disorder		Duration at the time of admission	Present episode		External stress	
			Age of onset	No. of episodes last episode		Best characterized	Onset was		
2/5	73		44	3	3 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent	
	74		52	0	2 months	Different prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	75		47	3	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	76		32	0	4 months	First occurrence	Subacute (>= 2 weeks)	Probably present	
	77		22	3	1 year	Similar prev. cond.	Acute (< 2 weeks)	Probably present	
	78		37	20	3 months	Chronic condition	Acute (< 2 weeks)	Definitely present	
	2/6	55		57	0	3 months	First occurrence	Insidious (>= 3 months)	Probably present
		56		59	0	3 months	First occurrence	Insidious (>= 3 months)	Probably present
57			50	1	3 months	Different prev. cond.	Insidious (>= 3 months)	Probably present	
58			59	1	3 months	Different prev. cond.	Insidious (>= 3 months)	Probably present	
59			33	0	1 month	First occurrence	Insidious (>= 3 months)	Probably present	
60			34	1	2 months	Different prev. cond.	Subacute (>= 2 weeks)	Probably present	
3/1		61		22	0	1 month	First occurrence	Subacute (>= 2 weeks)	Probably present
		62	Yes	5 weeks and 5 days	5 weeks and 5 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
		63	Yes	4 weeks and 10 days	4 weeks and 10 days	First occurrence	Acute (< 2 weeks)	Probably present	
		64		44	3	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	65	Yes	40	2	4 weeks	First occurrence	Subacute (>= 2 weeks)	Absent	
	66		40	2	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	139		27	2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	140		53	2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	141		37	1	6 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	142	Yes	39	3	1 month and 2 weeks	First occurrence	Acute (< 2 weeks)	Absent	
	143	Yes	51	2	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	144	Yes	54	2	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
3/2	65/A		19	1	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	3/3	67		34	3	3 months and 2 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
		68		38	2	1 month and 2 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
		69		24	3	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
		70		40	2	1 month	First occurrence	Subacute (>= 2 weeks)	Probably present
		71		23	1	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
		72		31	1	1 month and 2 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present
		3/4	79		42	1	4 months	Similar prev. cond.	Subacute (>= 2 weeks)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Age of onset	History of mental disorder		Duration at the time of admission	Best characterized	Present episode		External stress
			No. of episodes	Duration of last episode			Onset was		
3/4	80	0	0	1 month and 3 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	Definitely present	
	81	0	0	4 months	First occurrence	Insidious (>= 3 months)	Definitely present	Definitely present	
	82	0	0	10 weeks	First occurrence	Acute (< 2 weeks)	Probably present	Probably present	
	83	1	1 year	4 months	Different prev. cond.	Insidious (>= 3 months)	Probably present	Probably present	
	84	1	4 months	5 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	Definitely present	
	85	1	4 months	1 month and 2 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present	
	86	1	2 months and 2 weeks	1 month and 4 week	First occurrence	Insidious (>= 3 months)	Probably present	Probably present	
	87	1	2 months and 1 week	2 months and 3 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present	
	88	3	2 months	3 months and 1 week	First occurrence	Insidious (>= 3 months)	Definitely present	Definitely present	
	89	0	0	3 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	Definitely present	
	90	0	0	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	Probably present	
	457	2	6 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	Probably present	
	458	4	4 months	2 months	Chronic condition	Insidious (>= 3 months)	Probably present	Probably present	
	459	4	4 months	1 month	Chronic condition	Insidious (>= 3 months)	Probably present	Probably present	
	460	0	0	3 months	First occurrence	Insidious (>= 3 months)	Probably present	Probably present	
	461	0	0	2 months and 3 weeks	First occurrence	Insidious (>= 3 months)	Definitely present	Definitely present	
	462	0	0	2 months	First occurrence	Subacute (>= 2 weeks)	Definitely present	Definitely present	
	4/1	91	6	4 months	4 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present	Probably present
		92	13	3 months	2 months	Similar prev. cond.	Acute (< 2 weeks)	Probably present	Probably present
93		3	1 year	3 months	First occurrence	Insidious (>= 3 months)	Probably present	Probably present	
94		37	2	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	Probably present	
95		44	2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	Absent	
96		40	10	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present	
115		51	4	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present	
116		39	1	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present	
117		36	5	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present	
118		22	2	3 months	First occurrence	Subacute (>= 2 weeks)	Definitely present	Definitely present	
119		44	1	3 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	Definitely present	
120		31	1	6 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	Definitely present	
143		40	1	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present	
146		55	0	3 months	First occurrence	Subacute (>= 2 weeks)	Absent	Absent	
147		34	3	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	Absent	
148		42	6	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	Absent	
149		56	0	6 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present	Probably present	
150	40	5	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	Absent		
4/2	98/A	3	3 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	Absent	
	99/A	42	1 month	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	Absent	
	104	46	6 months	3 months	Chronic condition	Insidious (>= 3 months)	Absent	Absent	
4/3	97	1	10 months	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present	
	98	2	9 months and 3 weeks	3 months and 2 weeks	Similar prev. cond.	Insidious (>= 3 months)	Absent	Absent	
	99	8	2 months	2 months	Chronic condition	Subacute (>= 2 weeks)	Absent	Absent	
	100	5	3 months and 2 weeks	5 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	Probably present	
	101	43	1	6 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	Probably present

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Unknown	History of mental disorder		Duration at the time		Present episode		External stress
			Age of onset	No. of episodes	Duration of last episode	Best characterized	Onset was		
4/4	109		27	1	6 weeks	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	110		53	3	4 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	111		49	6	3 months	2 months	Chronic condition	Insidious (>= 3 months)	Absent
	112		22	1	6 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	113		22	2	4 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	114		32	8	2 months	1 month and 2 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	175		40	3	2 months	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	176		14	2	2 months	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	177		52	3	2 months	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	178		20	2	2 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
OO	179		28	1	2 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	180		39	1	6 weeks	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
5/1	127		20	4	3 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	128		30	3	2 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	129		18	1	3 weeks	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	130		18	1	3 weeks	2 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	131		25	20	4 weeks	2 months	Chronic condition	Subacute (>= 2 weeks)	Probably present
	132	Yes				4 months	First occurrence	Insidious (>= 3 months)	Probably present
5/2	121		17	3	2 months and 2 weeks	3 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	125		39	5	2 months	11 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
5/3	133		51	2	8 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	134		20	4	7 weeks	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	135		42	3	5 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	136		37	7	10 weeks	8 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	137		18	5	2 months	2 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present
	138		31	0		1 month and 3 weeks	First occurrence	Insidious (>= 3 months)	Definitely present
6/1	151		43			3 months	First occurrence	Subacute (>= 2 weeks)	Probably present
	152		40	2	6 months	1 month	Different prev. cond.	Subacute (>= 2 weeks)	Probably present
	153		43	4	5 weeks	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	154		26	2	4 months	1 month	First occurrence	Subacute (>= 2 weeks)	Probably present
	155		26	1	6 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
6/2	157		25	10	4 months	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	158		32	5	4 months	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	159		44	1	2 years	6 weeks	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	160		34			3 months	First occurrence	Insidious (>= 3 months)	Probably present
	161	Yes				3 months	First occurrence	Subacute (>= 2 weeks)	Probably present
	162		47			3 months	First occurrence	Insidious (>= 3 months)	Definitely present

9550082

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Unknown	History of mental disorder		Duration at the time of admission	Present episode		External stress
			Age of onset	No. of episodes last episode		Best characterized	Onset was	
6/2	169		40	3 months	1 month	Subacute (>= 2 weeks)	Absent	
	170		2	2 months	3 months and 3 weeks	Subacute (>= 3 months)	Absent	
	171		0		First occurrence	Insidious (>= 3 months)	Absent	
	172		0		First occurrence	Insidious (>= 3 months)	Probably present	
	173		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	174		2	2 months	30 days	Subacute (>= 2 weeks)	Absent	
6/3	163		1	1 year	3 months	Insidious (>= 3 months)	Probably present	
	164		2	6 months	3 months	Insidious (>= 3 months)	Probably present	
	165		2	6 months	2 months	Insidious (>= 3 months)	Probably present	
	166		2	6 months	2 months	Insidious (>= 3 months)	Probably present	
	167		2	3 months	2 months	Subacute (>= 2 weeks)	Probably present	
	168		5	1 year	2 months	Subacute (>= 2 weeks)	Probably present	
	169		3	1 year	2 months	Subacute (>= 2 weeks)	Probably present	
	170		5	6 months	2 months	Subacute (>= 2 weeks)	Probably present	
	171		5	6 months	2 months	Subacute (>= 2 weeks)	Probably present	
	172		2	6 months	2 months	Subacute (>= 2 weeks)	Probably present	
	173		4	8 months	2 months	Subacute (>= 2 weeks)	Probably present	
	174		2	6 months	2 months	Subacute (>= 2 weeks)	Probably present	
	175		0		4 weeks	Subacute (>= 2 weeks)	Probably present	
	176		1	4 months	4 weeks	Subacute (>= 2 weeks)	Probably present	
	177		2	6 months	2 months	Subacute (>= 2 weeks)	Probably present	
	7/02	181	Yes	7	3 months	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present
182		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
183		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
184		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
185		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
186		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
187		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
188		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
189		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
190		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
191		Yes	1	1 month and 2 weeks	Subacute (>= 2 weeks)	Probably present		
7/03	192		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	193		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	194		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	195		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	196		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	197		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	198		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	199		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	200		0		First occurrence	Subacute (>= 2 weeks)	Absent	
	201		0		First occurrence	Subacute (>= 2 weeks)	Absent	
7/04	202	Yes	1	3 months and 1 week	4 weeks	Subacute (>= 2 weeks)	Probably present	
	203	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	
	204	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	
	205	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	
	206	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	
	207	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	
	208	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	
	209	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	
	210	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	
	211	Yes	1	3 months and 1 week	8 weeks	Subacute (>= 2 weeks)	Probably present	

9550082

PHARMACIA CNS R&D
 BEROKETINE - PROTOCOL 20124/015
 Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Unknown	History of mental disorder		Duration at the time of admission	Best characterized	Present episode		External stress
			Age of onset	No. of episodes last episode			Onset was	Duration	
7/04	194	Yes			3 months	First occurrence	Insidious (>= 3 months)	Absent	
	195	Yes			2 months	First occurrence	Insidious (>= 3 months)	Absent	
	196	Yes			3 months	First occurrence	Insidious (>= 3 months)	Absent	
	197	Yes			3 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	198	Yes			3 months	First occurrence	Insidious (>= 3 months)	Absent	
	199	Yes			2 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	200	Yes			2 months and 2 weeks	First occurrence	Subacute (>= 2 weeks)	Absent	
	201	Yes			2 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	202	Yes			3 months	First occurrence	Insidious (>= 3 months)	Definitely present	
	203	Yes			2 months	First occurrence	Subacute (>= 2 weeks)	Absent	
7/05	205		2	2 months	6 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	206		3	3 months	7 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	207	Yes			2 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	208		1	2 months and 2 weeks	6 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	209	Yes			6 weeks	First occurrence	Subacute (>= 2 weeks)	Absent	
	210	Yes			7 weeks	First occurrence	Subacute (>= 2 weeks)	Absent	
	561		4	4 weeks	4 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	562		3	3 months	3 months	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	563		2	3 months	3 months	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	564		3	4 months	3 months	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
078	565		2	4 months	5 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	566	Yes			3 months	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
	529		3	3 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
	530		6	4 weeks	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
7/07	531		1	2 months	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	532	Yes			4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	533	Yes			4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	534	Yes			5 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present	
	211		4	4 weeks	45 days	Similar prev. cond.	Acute (< 2 weeks)	Absent	
8	212		3	1 week	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	213		4	2 months	40 days	Similar prev. cond.	Acute (< 2 weeks)	Absent	
	214		4	1 month	45 days	Similar prev. cond.	Acute (< 2 weeks)	Absent	
	215		1	4 weeks	35 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	216		4	4 weeks	30 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	217		4	1 month	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	218		1	2 months	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	219		1	2 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	220		2	4 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	221		3	1 month	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	222		2	1 month	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	223		3	2 months	28 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	224		1	3 months	35 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	225		1	6 weeks	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	

9550082

7

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Unknown	History of mental disorder		Duration at the time of admission	Best characterized	Present episode		External stress
			Age of onset	No. of episodes last episode			Onset was	Duration	
8	226		2	3 months	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	227		1	2 months	35 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	228		1	6 weeks	35 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	229		2	2 months	40 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	230		3	5 weeks	35 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	231		1	2 months	40 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	232		1	1 month	40 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	233		1	2 months	45 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	234		2	6 months	40 days	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	8/A	235		7	3 months	2 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
		236		3	2 months	3 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent
		237		5	3 months	1 month	Similar prev. cond.	Acute (< 2 weeks)	Absent
		238		3	1 month	3 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent
239			2	3 months	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
240			6	1 month	3 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent	
241			1	2 months	1 month and 2 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Absent	
242			3	1 month	3 weeks	Chronic condition	Acute (< 2 weeks)	Absent	
243			2	3 months	2 months	Similar prev. cond.	Acute (< 2 weeks)	Absent	
244			4	10 weeks	3 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
9	241		2	3 months	4 months	Similar prev. cond.	Insidious (>= 3 months)	Absent	
	242		4	3 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	243		4	3 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	244		13	2 months	4 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent	
	245		2	8 months	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	246		11	1 month	4 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent	
	247		4	5 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	248		1	6 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	249		3	3 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	250		3	6 months	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	251		22	2 months	3 months	First occurrence	Acute (< 2 weeks)	Definitely present	
	252		4	5 months	1 month	Similar prev. cond.	Acute (< 2 weeks)	Absent	
	253		2	2 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	254		15	3 months	3 months	Similar prev. cond.	Acute (< 2 weeks)	Definitely present	
	255		2	3 months	2 months	Different prev. cond.	Acute (< 2 weeks)	Absent	
	256		2	3 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	257		23	2 months	2 months	First occurrence	Subacute (>= 2 weeks)	Probably present	
258		29	2 months	2 months	First occurrence	Subacute (>= 2 weeks)	Probably present		
11	319		3	3 months	3 months	First occurrence	Subacute (>= 2 weeks)	Probably present	
	320		1	5 months	1 month	Similar prev. cond.	Acute (< 2 weeks)	Definitely present	
	321		4	6 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	322		1	2 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	323		3	3 months	4 months	First occurrence	Insidious (>= 3 months)	Absent	
	324		0	0	3 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	324		0	0	3 months	First occurrence	Subacute (>= 2 weeks)	Definitely present	
	325		58	0	3 months	First occurrence	Subacute (>= 2 weeks)	Definitely present	

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8

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Unknown	History of mental disorder		Duration at the time of admission	Best characterized	Present episode		External stress
			Age of onset	No. of episodes last episode			Onset was	Onset was	
11	326		47	3	1 year	Similar prev. cond.	Insidious (>= 3 months)	Absent	
	327		23	1	3 months	Similar prev. cond.	Insidious (>= 3 months)	Absent	
	328		30	1	6 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	329		36	2	1 year	Chronic condition	Subacute (>= 2 weeks)	Definitely present	
	330		44	0	3 months	First occurrence	Acute (< 2 weeks)	Definitely present	
	331		44	1	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	332		63	1	3 months	Similar prev. cond.	Acute (< 2 weeks)	Definitely present	
	333		33	0	2 months	First occurrence	Acute (< 2 weeks)	Definitely present	
	334		36	1	3 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	335		37	2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	336		37	1	6 months	Similar condition	Insidious (>= 3 months)	Definitely present	
12	337		24	1	4 months	Similar prev. cond.	Insidious (>= 3 months)	Absent	
	338		29	0	2 months	First occurrence	Acute (< 2 weeks)	Definitely present	
	367		47	1	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
13	368		40	0	2 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	369		33	2	3 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	370		51	2	8 weeks	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
	371		48	3	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	372		19	2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	373		46	2	6 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	374		20	1	8 months	Similar prev. cond.	Insidious (>= 3 months)	Absent	
	375		45	1	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	42		42	2	6 months	Different prev. cond.	Insidious (>= 3 months)	Definitely present	
	14	14		16	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	15	15		14	10 months	Chronic condition	Subacute (>= 2 weeks)	Absent	
16	16		37	1 month	Chronic condition	Subacute (>= 2 weeks)	Absent		
17	17		15	6 months	Chronic condition	Insidious (>= 3 months)	Absent		
18	18		40	5 months	Chronic condition	Insidious (>= 3 months)	Absent		
409	409		54	2 months	Chronic condition	Subacute (>= 2 weeks)	Absent		
410	410		29	2 months	Chronic condition	Subacute (>= 2 weeks)	Absent		
411	411		27	6 months	Chronic condition	Insidious (>= 3 months)	Probably present		
423	423		16	10 months	Chronic condition	Subacute (>= 2 weeks)	Absent		
14	19		28	1	2 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
	20		36	1	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	21		35	4	1 month	Similar prev. cond.	Acute (< 2 weeks)	Definitely present	
15	25		49	2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	26		24	4	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	27		49	3	10 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	28		35	6	10 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	29		45	1	2 months	First occurrence	Insidious (>= 3 months)	Probably present	
	30		37	2	1 year	Similar prev. cond.	Insidious (>= 3 months)	Absent	
	403	403		44	16 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present	

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9

PHARMACIA CNS B&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	History of mental disorder		Duration at the time of admission	Present episode		External stress
		Age of onset	No. of episodes		Best characterized	Onset was	
15	404	42		12 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present
	405	49		14 weeks	First occurrence	Insidious (>= 3 months)	Definitely present
	406	31		8 weeks	First occurrence	Acute (< 2 weeks)	Definitely present
	408	23	1	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	418	22	2	2 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
	419	57	2	8 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
		27	1	10 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present

843

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1

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

- A. At least five of the following symptoms have been present during the same two-week period and represent a change from previous functioning: at least one of the symptoms is either 1) depressed mood or 2) loss of interest or pleasure.
- 1) depressed mood most of day, nearly every day, as indicated by subjective account or observation by others
 - 2) markedly diminished interest or pleasure in all, or almost all, activities most of day, nearly every day (as indicated either by subjective account or observation by others of apathy most of the time)
 - 3) significant weight loss or weight gain when not dieting (e.g. more than 5% of body weight in a month), or decrease or increase in appetite nearly every day
 - 4) insomnia or hypersomnia nearly every day
 - 5) psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
 - 6) fatigue or loss of energy nearly every day
 - 7) feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
 - 8) diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
 - 9) recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide
- B. 1) it cannot be established that an organic factor initiated and maintained the disturbance
2) the disturbance is not a normal reaction to the death of a loved one
- C. At no time during the disturbance have there been delusions or hallucinations for as long as two weeks in the absence of prominent mood symptoms (i.e., before the mood symptoms developed or after they have remitted)
- D. Not superimposed on Schizophrenia, Schizophreniform, Disorder, Delusional Disorder, or Psychotic Disorder NOS.

8
7
4

9550082

3

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PHARMACIA CNS R&D
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient Sex	Age	DSM-III-R	A items										B items		C		D							
				Present	1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present	Present	Present					
2/5	73	Male	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	74	Male	52	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	75	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	76	Female	32	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2/6	77	Male	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	78	Female	51	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	55	Female	57	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	56	Female	59	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3/1	57	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	58	Female	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	59	Male	33	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	60	Female	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	61	Male	22	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	62	Female	24	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	63	Male	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	64	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	65	Male	62	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	66	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	139	Male	31	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	140	Male	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	141	Female	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	142	Female	20	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	143	Female	44	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	144	Female	26	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
451	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
452	Male	44	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
453	Female	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
454	Male	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
455	Female	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
456	Female	39	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
3/2	65/A	Female	21	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3/3	67	Male	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	68	Male	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	69	Male	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	70	Male	40	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	71	Female	24	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	72	Male	31	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3/4	79	Female	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	Present	A Items									B Items		C		D	
						1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present	Present
3/4	80	Male	46	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	81	Female	35	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	82	Male	49	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	83	Male	49	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	84	Female	27	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	85	Female	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	86	Male	34	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	87	Female	33	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	88	Male	53	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	89	Female	49	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	90	Male	47	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	457	Female	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	458	Female	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	459	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
460	Male	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
461	Female	45	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
462	Female	39	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
4/1	91	Female	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	92	Female	28	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	93	Male	18	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	94	Female	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	95	Female	42	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	96	Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	115	Female	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	116	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	117	Female	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	118	Female	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	119	Female	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	120	Female	35	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	143	Female	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	146	Female	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
147	Female	65	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
148	Female	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
149	Female	56	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
150	Male	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
4/2	93/A	Male	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	99/A	Male	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	104	Male	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
4/3	97	Male	42	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	98	Female	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	99	Female	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	100	Female	24	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	101	Male	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

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5

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 3.0
 DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	A items										B items		C		D		
					Present	1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present	Present	Present
4/4	109	Female	28	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	110	Male	64	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	111	Male	65	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	112	Male	23	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	113	Male	23	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	114	Female	62	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	175	Female	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	176	Female	31	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	177	Female	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	178	Female	35	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
179	Female	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
180	Male	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
5/1	127	Male	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	128	Female	33	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	129	Male	19	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	130	Male	30	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	131	Female	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	132	Male	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
5/2	121	Female	20	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	125	Male	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
5/3	133	Male	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	134	Female	31	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	135	Female	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	136	Female	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	137	Female	32	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
6/1	151	Male	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	152	Female	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	153	Male	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
6/2	154	Female	26	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	155	Male	63	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	156	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	157	Male	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
158	Female	37	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
159	Male	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
160	Male	35	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
161	Female	20	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
162	Male	47	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

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6

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	Present	A items									B items		C		D		
						1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present		
6/2	169	Female	53	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	170	Male	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	171	Female	54	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	172	Female	72	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	173	Male	44	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
6/3	174	Male	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	163	Male	37	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	164	Male	29	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	165	Female	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	166	Female	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
7/02	181	Male	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	182	Male	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	183	Male	51	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	184	Female	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	185	Male	59	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	186	Male	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	535	Male	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	536	Female	32	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	187	Female	49	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	188	Male	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	189	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	7/03	190	Male	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		191	Female	48	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
192		Female	63	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
523		Female	35	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
524		Female	28	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
525		Female	35	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
526		Female	37	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
527		Female	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
7/04	193	Female	64	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

6100

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	Present	A items									B items		C		D	
						1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present	Present
7/04	194	Male	28	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	195	Female	60	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	196	Female	50	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	197	Male	30	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	198	Female	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	199	Male	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	200	Male	40	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	201	Female	59	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
7/05	202	Male	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	203	Female	41	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	204	Female	58	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	205	Male	61	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	206	Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	207	Female	62	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	208	Male	42	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	209	Male	53	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
7/07	210	Male	64	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	541	Female	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	542	Male	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	543	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	544	Female	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	545	Male	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	546	Female	61	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	529	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
8	530	Female	53	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	531	Female	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	532	Female	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	533	Male	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	534	Female	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	211	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	212	Female	65	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	213	Male	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	214	Female	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	215	Female	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	216	Male	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	217	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	218	Female	53	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	219	Female	23	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	220	Female	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	221	Male	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
222	Female	64	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
223	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
224	Female	25	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
225	Male	20	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	A items							B items		C		D		
					Present	1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present
8	226	Male	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	227	Male	64	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	228	Male	31	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	229	Female	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	230	Female	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	231	Male	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	232	Male	29	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	233	Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	234	Female	65	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	8/A	235	Female	62	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X
236		Female	44	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
237		Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
238		Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
239		Female	42	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
240		Female	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
553		Female	36	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
554		Male	60	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
555		Female	64	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
556		Male	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
9	241	Female	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	242	Female	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	243	Female	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	244	Female	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	245	Female	44	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	246	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	247	Female	33	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	248	Male	37	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	249	Female	42	296.5	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	250	Female	51	296.5	X	X	X	X	X	X	X	X	X	X	X	X	X	X
11	319	Male	45	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	320	Male	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	321	Male	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	322	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	323	Male	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	324	Male	31	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	325	Male	58	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	A items									B items		C		D	
					Present	1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present
11	326	Male	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	327	Male	33	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	328	Female	29	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	329	Female	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	330	Male	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	331	Male	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	332	Male	64	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	333	Male	33	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	334	Female	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	335	Male	33	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
12	336	Female	42	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	337	Female	25	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	338	Male	29	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	367	Female	62	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	368	Female	40	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	369	Female	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	370	Male	60	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	371	Female	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	372	Male	36	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	373	Male	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
13	374	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	375	Male	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	44	Male	44	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	14	Male	28	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	15	Female	23	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	16	Male	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	17	Male	35	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	18	Male	51	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	409	Male	61	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	410	Male	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14	411	Female	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	423	Male	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	19	Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
20	Female	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
21	Female	59	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
15	25	Female	60	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	26	Male	36	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	27	Female	53	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	28	Female	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	29	Male	47	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	50	Female	44	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	403	Female	44	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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PHARMACIA CNS RRD
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 3.0
 DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	A Items									B Items		C		D						
					Present	1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present	Present	Present			
15	404	Female	42	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	405	Female	49	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	406	Male	31	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	407	Female	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	408	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	418	Female	63	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	419	Female	30	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
1	6	Female	36	OTHER GU NEOPLASM NOS	
	11	Female	39	FLU W RESP MANIFEST NEC	CONGENITAL ANOMALIES NEC
	413	Male	51	ANKYLOSING SPONDYLITIS PURE HYPERCHOLESTEROLEM	
	416	Female	41	GASTRITIS/DUODENITIS NOS	ANEMIA NOS HYPOTHYROIDISM NOS
	421	Male	57		PURE HYPERGLYCEMIDEMIA
	422	Male	44	ARTHROPATHY NOS	PURE HYPERCHOLESTEROLEM
2/1	49	Female	53	SPONDYLOSIS NOS OTHER GU NEOPLASM NOS OTHER GU NEOPLASM NOS	
2/2	45	Female	26	PRURITIC DISORDER NOS ALLERGIC RHINITIS NOS	
	47	Female	35	BRAIN INJURY NEC CHOLELITH W CHOLECYST NEC BENIGN NEOPLASM BREAST	
	48	Female	31	UNSPECIFIED ABORTION	
2/3	36/A	Male	53	AC INFECT POLYNEURITIS	
	39	Female	52	DIARRHEA OF INFECT ORIG ALLERGY, UNSPECIFIED	
	40	Female	59	ALCOHOL DEPENDENCE SYNDR ANOREXIA NERVOSA URIN TRACT INFECTION NOS	URIN TRACT INFECTION NOS
	41	Male	25		ABN LIVER FUNCTION STUDY

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
2/3	42	Female	40	FX TARSUS/METAPARS NEC-CL URIN TRACT INFECTION NOS OBESITY	ALCOHOL LIVER DAMAGE NOS URIN TRACT INFECTION NOS ALCOHOL DEPENDENCE SYNDR
2/4	32	Male	59	BACKACHE NOS ATRIAL FIBRILL/FLUTTER	ATRIAL FIBRILL/FLUTTER
	33	Male	38		ALCOHOL DEPENDENCE SYNDR
	34	Female	55	HYPOTENSION NOS CIRCULATORY DISEASE NOS	
	35	Female	64	PAIN IN LIMB	
	36	Female	57	HYPERTENSION NOS DIABETES MELLITUS UNCOMP	HYPOTENASSEMIA
2/5	74	Male	52	ARTERITIS NOS	
3/1	453	Female	55	DIABETES MELLITUS UNCOMP PURE HYPERCHOLESTEROLEM HYPERTENSION NOS	
	454	Male	56	SENILE CATARACT RETINAL DETACHMENT NOS DIABETES MELLITUS UNCOMP	
	456	Female	39	PANNICULITIS OF NECK TACHYCARDIA NOS PREMATURE BEATS THROMBOPHLEBITIS LEG NOS	PALPITATIONS HYPOTENSION NOS
3/3	69	Male	34	ACUTE POLIOMYELITIS NOS	
	70	Male	40	SPONDYLOSIS NOS	
	71	Female	26	HEADACHE	
3/4	83	Male	49	OBSTRUCT CHR BRONCHITIS	URIN TRACT INFECTION NOS

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PHARMACIA CNS 22D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
3/4	87	Female	33	ASTHMA NOS	
	457	Female	48	BENIGN NEO UTERUS NOS METRORRHAGIA	
	459	Female	57	HEPATITIS A W/O COMA DIAPHRAGMATIC HERNIA CERVICALGIA SCIATICA	
	461	Female	45	PULMONARY TB NOS FRACTURE NOS	
	462	Female	39	INFERTILITY-TUBAL ORIGIN	
4/1	92	Female	28		URIN TRACT INFECTION NOS
	117	Female	59	HYPOTHYROIDISM NOS	
	146	Female	55		HYPERTENSION NOS
	147	Female	65		URIN TRACT INFECTION NOS
	148	Female	59	TACHYCARDIA NOS	
4/4	110	Male	64	LOWER LEG INJURY NOS	
	112	Male	23		URIN TRACT INFECTION NOS
	178	Female	35	DIS IRON METABOLISM FX BILLOLELAR-CLOSED	DIS IRON METABOLISM
5/1	152	Male	38	ALCOHOL DEPENDENCE SYNDR	
5/3	198	Female	31		ABN LIVER FUNCTION STUDY

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
6/1	152	Female	56	ALCOHOL DEPENDENCE SYNDR	
	155	Male	63	PURE HYPERCHOLESTEROLEM	
	156	Female	41	HEPATITIS NOS HYPERTENSION NOS	
6/2	160	Male	35	PNEUMONIA, ORGANISM NOS	
	161	Female	20	HEARING LOSS NOS	URIN TRACT INFECTION NOS
	169	Female	53	HYPERTENSION NOS MALIGN NEOPL BREAST NOS	
7/02	182	Male	57	DUODENAL ULCER NOS	
	183	Male	51	GOITER NOS HYPERTENSION NOS	
	185	Male	59	DIABETES MELLITUS UNCOMP	
7/03	187	Female	49	GOITER NOS	GOITER NOS
	191	Female	48	OBESITY CARDIAC DYSRHYTHMIAS NEC	
	523	Female	35	STAMMERING STUTTERING PREMENSTRUAL TENSION	
	524	Female	26	EMOTIONAL DIS CHILD NOS	
	525	Female	35	OBESITY	
	526	Female	57	NYALGIA AND MYOSITIS NOS DISC DISPLACEMENT NOS OBESITY	

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PHARMACIA CNS R8D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
7/03	527	Female	36	HEADACHE	
7/04	193	Female	64	PURE HYPERCHOLESTEROLEM	
	194	Male	28	CHRONIC LIVER DIS NEC	
	198	Female	55	HYPERLIPIDEMIA NEC/NOS	
7/05	205	Male	61	VARICOSE VEIN OF LEG NOS	
	206	Female	52	CALCULUS OF KIDNEY GOUTER NOS APPENDICITIS NOS	
	207	Female	62	BACKACHE NOS APPENDICITIS NOS GASTRITIS/DUODENITIS NOS	
	210	Male	64	HEMORRHOIDS NOS CERVICOBRACHIAL SYNDROME	
	541	Female	59	CIRCULATORY DISEASE NOS	
	542	Male	47	DISC DISPLACEMENT NOS VERTEBRAL FX NOS-CLOSED STOMACH ULCER NOS	
	543	Male	50	HYPERLIPIDEMIA NEC/NOS CIRCULATORY DISEASE NOS INGUIN HERNIA N OBSTRUCT	
	544	Female	56	SPINAL CORD INJURY NOS BENIGN NEOPLASM SKIN NOS FLAT FOOT	
	545	Male	55	HYPERLIPIDEMIA NEC/NOS ABN BLOOD CHEMISTRY NEC	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
7/05	546	Female	61	HYPERLIPIDEMIA NEC/NOS BONE/CARTIL DIS NEC/NOS CIRCULATORY DISEASE NOS	
8	215	Female	46	INTEST MALABSORPTION NEC	
	218	Female	53	MALIGN NEOPL BREAST NOS OTHER GU NEOPLASM NOS	
	219	Female	23	OTHER SKIN ANOMALIES	
8/A	235	Female	62	OSTEOPOROSIS	
	238	Female	52	OSTEOPOROSIS	
	239	Female	62	CHR ISCHEMIC HRT DIS NEC	
	554	Male	60	DIABETES MELLITUS UNCOMP HYPERTENSION NOS	
	555	Female	64	HYPERTENSION NOS	
9	241	Female	43	VARICOSE VEIN OF LEG NOS CERVICITIS ACUTE APPENDICITIS NOS	
	244	Female	56	DUODENAL ULCER NOS	
	249	Female	42		ABN URINE FINDINGS NEC
	250	Female	51	HYPERTENSION NOS	
	252	Female	61	HYPERTENSION NOS	
11	325	Male	58	ACUTE POLIOMYELITIS NOS	

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PEARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
11	329	Female	40	HYPERTENSION NOS	
	332	Male	64	HYPERTENSION NOS	
	333	Male	33	OBESITY	
	336	Female	42	OTHER GU NEOPLASM NOS PNEUMONIA, ORGANISM NOS	
12	367	Female	62	HYPERTENSION NOS	
	370	Male	60	HYPERTENSION NOS	
	372	Male	36	OBESITY	
	373	Male	52	STOMACH ULCER NOS	
	374	Female	34	MIGRAINE NOS	
	375	Male	47	DIGESTIVE NEOPLASM NOS AC PERICARDITIS NEC/NOS	
13	13	Male	44	PNEUMOTHORAX ACUTE BRONCHITIS	
	15	Female	29	BRONCHITIS NOS PNEUMONIA, ORGANISM NOS	
	16	Male	52	OTHER PROLAPASIS	
14	21	Female	59	THYROTOXICOSIS NOS	
15	25	Female	60	SARCIDOSIS DIVERTICULA OF COLON	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
15	27	Female	53	OTHER GI NEOPLASM NOS MALIGN NEOPL BREAST NOS ACUTE APPENDICITIS NOS PEPTIC ULCER NOS	
	29	Male	47	THORAC/LUMB DISC DISPLAC	
	403	Female	44	CERVICAL SPONDYLOSIS	
	404	Female	42	CHONDRODYSSTROPHY	
	405	Female	49	PARAPSORIASIS	
	418	Female	63	OSTEITIS DEFORMANS NOS	
	419	Female	30	TRUNK INJURY NOS BONE/CARTIL DIS NEC/NOS ASTHMA NOS	

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

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Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
1	1	Female	Screen		Not done	
	2	Male	Screen		Not done	
	3	Male	Screen	02/05/91	Normal	
	4	Male	Screen	04/06/91	Normal	
	5	Female	Screen	12/06/91	Normal	
	6	Female	Screen	24/05/91	Normal	
	7	Female	Screen	28/08/91	Normal	
	8	Male	Screen	06/09/91	Normal	
	9	Female	Screen	28/11/91	Normal	
	10	Male	Screen	25/09/91	Normal	
	11	Female	Screen	10/10/91	Normal	
	12	Female	Screen	25/10/91	Normal	
	412	Male	Screen	12/11/91	Normal	
	413	Male	Screen	03/12/91	Normal	
	414	Female	Screen	20/01/92	Normal	
	415	Male	Screen	14/01/92	Normal	
	416	Female	Screen	20/01/92	Normal	

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2

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function Abnormality
1	421	Male	Screen	27/02/92	Normal	
	422	Male	Screen	05/08/92	Normal	
2/1	49	Female	Screen	16/05/91	Normal	
	50	Female	Screen	24/12/91	Normal	
	51	Female	Screen	28/01/92	Normal	
2/2	43	Female	Screen		Not done	
	44	Female	Screen		Not done	
	45	Female	Screen		Not done	
	46	Female	Screen		Not done	
	47	Female	Screen	13/03/92	Normal	
	48	Female	Screen	03/04/92	Normal	
2/3	36/A	Male	Screen	06/03/91	Normal	
	37	Female	Screen	23/03/91	Normal	
	38	Male	Screen	23/05/91	Normal	
	39	Female	Screen	06/08/91	Normal	
	40	Female	Screen	22/10/91	Normal	
	41	Male	Screen	10/10/91	Normal	

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
2/3	42	Female	Screen	07/05/92	Normal	
2/4	31	Male	Screen		Not done	
	32	Male	Screen		Not done	
	33	Male	Screen		Not done	
	34	Female	Screen		Not done	
	35	Female	Screen		Normal	
	36	Female	Screen		Not done	
2/5	73	Male	Screen	28/01/92	Normal	
	74	Male	Screen	16/06/92	Normal	
	75	Male	Screen	03/09/92	Normal	
	76	Female	Screen	29/09/92	Normal	
	77	Male	Screen	15/09/92	Normal	
	78	Female	Screen	29/09/92	Normal	
2/6	55	Female	Screen		Not done	
	56	Female	Screen		Not done	
	57	Female	Screen		Not done	
	58	Female	Screen		Not done	

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4

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PEARHACIA CNS R8D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
2/6	59	Male	Screen			Not done
	60	Female	Screen			Not done
3/1	61	Male	Screen			Not done
	62	Female	Screen	12/04/91		Normal
	63	Male	Screen	10/05/91		Normal
	64	Female	Screen			Not done
	65	Male	Screen	11/09/91		Normal
	66	Male	Screen			Not done
	139	Male	Screen			Not done
	140	Male	Screen			Not done
	141	Female	Screen			Not done
	142	Female	Screen			Not done
	143	Female	Screen			Not done
	144	Female	Screen			Not done
	451	Female	Screen			Not done
	452	Male	Screen			Not done
	453	Female	Screen			Not done

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function Abnormality
3/1	454	Male	Screen		Not done	
	455	Female	Screen		Not done	
	456	Female	Screen		Not done	
3/2	65/A	Female	Screen	28/01/91	Normal	
3/3	67	Male	Screen	16/07/91	Normal	
	68	Male	Screen	13/01/92	Normal	
	69	Male	Screen	30/01/92	Normal	
	70	Male	Screen	10/04/92	Normal	
	71	Female	Screen	14/04/92	Normal	
	72	Male	Screen	19/07/92	Normal	
3/4	79	Female	Screen	13/05/91	Normal	
	80	Male	Screen	91	Normal	
	81	Female	Screen	14/05/91	Normal	
	82	Male	Screen	18/06/91	Normal	
	83	Male	Screen	17/10/90	Normal	
	84	Female	Screen	08/10/91	Normal	
	85	Female	Screen	29/10/91	Normal	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
3/4	86	Male	Screen	03/12/91	Normal	
	87	Female	Screen	06/12/91	Normal	
	88	Male	Screen		Not done	
	89	Female	Screen		Normal	
	90	Male	Screen	91	Normal	
	457	Female	Screen	19/05/92	Normal	
	458	Female	Screen	28/01/92	Normal	
	459	Female	Screen	01/06/92	Normal	
	460	Male	Screen		Not done	
	461	Female	Screen		Normal	
	462	Female	Screen		Normal	
4/1	91	Female	Screen	01/01/91	Normal	
	92	Female	Screen	05/08/91	Normal	
	93	Male	Screen	29/06/91	Normal	
	94	Female	Screen	29/06/91	Normal	
	95	Female	Screen	06/06/91	Normal	
	96	Female	Screen	30/08/91	Normal	

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
4/1	115	Female	Screen	04/05/92	Abnormal	PULMON CIRCULAT DIS NOS
	116	Female	Screen	07/05/92	Normal	
	117	Female	Screen	02/09/91	Normal	
	118	Female	Screen	19/05/92	Normal	
	119	Female	Screen		Not done	
	120	Female	Screen		Normal	
	145	Female	Screen	30/09/92	Normal	
	146	Female	Screen	31/07/92	Normal	
	147	Female	Screen	15/07/92	Normal	
	148	Female	Screen	10/09/92	Normal	
	149	Male	Screen	22/09/92	Normal	
	150	Male	Screen	23/09/92	Normal	
4/2	93/A	Male	Screen	22/02/91	Normal	
	99/A	Male	Screen	09/04/91	Normal	
	104	Male	Screen	11/06/91	Normal	
4/3	97	Male	Screen	15/04/91	Normal	
	98	Female	Screen	18/06/91	Normal	

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Abnormality	ENLARGEMENT LYMPH NODES
4/3	99	Female	Screen	07/08/91	Abnormal	
	100	Female	Screen	20/11/91	Normal	
	101	Male	Screen	16/03/92	Normal	
4/4	109	Female	Screen	05/06/91	Normal	
	110	Male	Screen	04/06/91	Normal	
	111	Male	Screen	10/05/91	Normal	
	112	Male	Screen	09/07/91	Normal	
	113	Male	Screen	06/09/91	Normal	
	114	Female	Screen	07/11/91	Normal	
	175	Female	Screen	05/02/91	Normal	
	176	Female	Screen	13/05/92	Normal	
	177	Female	Screen	24/04/92	Normal	
	178	Female	Screen	21/04/92	Normal	
	179	Female	Screen	09/09/92	Normal	
	180	Male	Screen	19/09/92	Normal	
5/1	127	Male	Screen	31/05/91	Normal	
	128	Female	Screen	13/06/91	Normal	

9550082

9

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function	
					Value	Abnormality
5/1	129	Male	Screen	23/12/91	Normal	
	130	Male	Screen	02/03/92	Normal	
	131	Female	Screen	24/03/92	Normal	
	132	Male	Screen	04/06/92	Normal	
5/2	121	Female	Screen		Not done	
	125	Male	Screen		Not done	
5/3	133	Male	Screen	26/11/91	Normal	
	134	Female	Screen	04/12/91	Normal	
	135	Female	Screen	08/01/92	Normal	
	136	Female	Screen		Not done	
	137	Female	Screen	13/05/92	Normal	
	138	Female	Screen	14/05/92	Normal	
6/1	151	Male	Screen	15/01/91	Abnormal	CHRONIC BRONCHITIS NOS
	152	Female	Screen	14/07/92	Abnormal	FX RIB/STERN/LARYN/TRACH
	153	Male	Screen	07/03/91	Normal	
	154	Female	Screen	18/03/92	Normal	
	155	Male	Screen		Not done	

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function - Abnormality
6/1	156	Female	Screen		Not done	
6/2	157	Male	Screen	23/04/91	Abnormal	LUNG DISEASE NEC
	158	Female	Screen	21/11/91	Normal	
	159	Male	Screen	11/07/91	Normal	
	160	Male	Screen	22/11/91	Normal	
	161	Female	Screen	06/02/92	Normal	
	162	Male	Screen	05/07/91	Normal	
	169	Female	Screen	22/10/91	Normal	
	170	Male	Screen	28/10/91	Normal	
	171	Female	Screen	18/07/92	Normal	
	172	Female	Screen		Not done	
	173	Male	Screen		Normal	
	174	Male	Screen	05/05/92	Normal	
6/3	163	Male	Screen		Not done	
	164	Male	Screen		Not done	
	165	Female	Screen	08/10/91	Normal	
	166	Female	Screen		Not done	

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11

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
6/3	167	Female	Screen	91	Normal	
	168	Female	Screen	25/11/92	Normal	
	505	Female	Screen	91	Normal	
	506	Female	Screen	06/01/92	Normal	
	507	Female	Screen	07/01/92	Normal	
	508	Female	Screen	01/02/92	Normal	
	509	Male	Screen		Not done	
	510	Female	Screen		Not done	
	511	Female	Screen		Not done	
	512	Female	Screen		Not done	
	513	Female	Screen		Not done	
7/02	181	Male	Screen		Not done	
	182	Male	Screen		Not done	
	183	Male	Screen		Not done	
	184	Female	Screen		Not done	
	185	Male	Screen		Not done	
	186	Male	Screen		Not done	

872

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

12

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function Abnormality
7/02	535	Male	Screen		Not done	
	536	Female	Screen		Not done	
7/03	187	Female	Screen		Not done	
	188	Male	Screen		Normal	
	189	Male	Screen	10/02/92	Normal	
	190	Male	Screen	21/01/92	Normal	
	191	Female	Screen		Normal	
	192	Female	Screen		Not done	
	523	Female	Screen	28/04/92	Normal	
	524	Female	Screen		Normal	
	525	Female	Screen		Normal	
	526	Female	Screen		Normal	
	527	Female	Screen		Normal	
	528	Female	Screen		Normal	
7/04	193	Female	Screen		Not done	
	194	Male	Screen		Not done	
	195	Female	Screen		Not done	

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

13

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PHARMACIA CMS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function - Abnormality
7/04	196	Female	Screen		Not done	
	197	Male	Screen		Not done	
	198	Female	Screen		Not done	
	199	Male	Screen		Not done	
	200	Male	Screen		Not done	
	201	Female	Screen		Not done	
	202	Male	Screen		Not done	
	203	Female	Screen		Not done	
	204	Female	Screen		Not done	
7/05	205	Male	Screen	30/12/91	Normal	
	206	Female	Screen	14/01/92	Normal	
	207	Female	Screen	21/01/92	Normal	
	208	Male	Screen	24/01/92	Normal	
	209	Male	Screen	29/01/92	Normal	
	210	Male	Screen	03/02/92	Normal	
	541	Female	Screen	02/03/92	Normal	
	542	Male	Screen	02/03/92	Normal	

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

14

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: S.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
7/05	543	Male	Screen	03/03/92	Normal	
	544	Female	Screen	04/03/92	Normal	
	545	Male	Screen	09/03/92	Normal	
	546	Female	Screen	10/03/92	Normal	
7/07	529	Female	Screen		Not done	
	530	Female	Screen		Not done	
	531	Female	Screen		Not done	
	532	Female	Screen		Not done	
	533	Male	Screen		Not done	
	534	Female	Screen		Normal	
8	211	Female	Screen		Not done	
	212	Female	Screen		Not done	
	213	Male	Screen		Not done	
	214	Female	Screen		Not done	
	215	Female	Screen		Not done	
	216	Male	Screen		Not done	
	217	Female	Screen		Not done	

875

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: S.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function Abnormality
8	218	Female	Screen		Not done	
	219	Female	Screen		Not done	
	220	Female	Screen		Not done	
	221	Male	Screen		Not done	
	222	Female	Screen		Not done	
	223	Female	Screen		Not done	
	224	Female	Screen		Not done	
	225	Male	Screen		Not done	
	226	Male	Screen		Not done	
	227	Male	Screen		Not done	
	228	Male	Screen		Not done	
	229	Female	Screen		Not done	
	230	Female	Screen		Not done	
	231	Male	Screen		Not done	
	232	Male	Screen		Not done	
	233	Female	Screen		Not done	
	234	Female	Screen		Not done	

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

16

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function	
					Value	Abnormality
8/A	235	Female	Screen		Not done	
	236	Female	Screen		Not done	
	237	Female	Screen		Not done	
	238	Female	Screen		Not done	
	239	Female	Screen		Not done	
	240	Female	Screen		Not done	
	553	Female	Screen		Not done	
	554	Male	Screen		Not done	
	555	Female	Screen		Not done	
	556	Male	Screen		Not done	
9	241	Female	Screen	12/02/91	Normal	
	242	Female	Screen		Not done	
	243	Female	Screen		Not done	
	244	Female	Screen		Not done	
	245	Female	Screen	18/02/91	Normal	
	246	Female	Screen		Not done	
	247	Female	Screen		Not done	

877

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

17

9550082

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Abnormality	
9	248	Male	Screen	21/03/91	Abnormal	
	249	Female	Screen		Not done	
	250	Female	Screen	12/03/91	Normal	
	251	Female	Screen	21/03/91	Normal	
	252	Female	Screen		Not done	
	253	Female	Screen	02/04/91	Normal	
	254	Female	Screen	04/04/91	Normal	
	255	Female	Screen	14/05/91	Normal	
	256	Female	Screen		Not done	
11	257	Male	Screen	23/06/91	Normal	
	258	Male	Screen	28/06/91	Normal	
	319	Male	Screen	25/07/91	Normal	
	320	Male	Screen	08/08/91	Normal	
	321	Male	Screen	23/08/91	Normal	
	322	Female	Screen	19/09/91	Normal	
	323	Male	Screen	07/11/91	Normal	
	324	Male	Screen	02/12/91	Normal	
						CHRONIC BRONCHITIS NOS

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18

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function - Abnormality	
11	325	Male	Screen	09/12/91	Normal		
	326	Male	Screen	15/01/92	Normal		
	327	Male	Screen	24/01/92	Normal		
	328	Female	Screen	29/01/92	Not done		
	329	Female	Screen	01/04/92	Normal		
	330	Male	Screen	07/04/92	Normal		
	331	Male	Screen	13/04/92	Normal		
	332	Male	Screen	13/05/92	Normal		
	333	Male	Screen	19/05/92	Normal		
	334	Female	Screen	21/05/92	Normal		
	335	Male	Screen	22/05/92	Normal		
	336	Female	Screen	16/06/92	Normal		
	337	Female	Screen	25/06/92	Normal		
	338	Male	Screen	15/07/92	Normal		
	12	367	Female	Screen	16/12/91	Normal	
		368	Female	Screen	07/01/92	Normal	
		369	Female	Screen	22/04/92	Normal	

879

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PHARMACIA CMS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Abnormality
12	370	Male	Screen	17/04/92	Normal
	371	Female	Screen	21/04/92	Normal
	372	Male	Screen	01/06/92	Normal
	373	Male	Screen	05/04/92	Normal
	374	Female	Screen		Normal
	375	Male	Screen	08/06/92	Normal
13	13	Male	Screen	12/04/91	Normal
	14	Male	Screen		Not done
	15	Female	Screen	01/07/91	Normal
	16	Male	Screen		Not done
	17	Male	Screen		Not done
	18	Male	Screen		Not done
	409	Male	Screen		Normal
	410	Male	Screen		Not done
	411	Female	Screen	01/04/92	Normal
	423	Male	Screen		Not done
14	19	Female	Screen	06/04/92	Normal

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

20

PHARMACIA CNS 8&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 5.0
 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
14	20	Female	Screen	27/04/92	Normal	
	21	Female	Screen	16/07/92	Normal	
15	25	Female	Screen	17/06/91	Abnormal	ENLARGEMENT LYMPH NODES
	26	Male	Screen	17/06/91	Normal	
	27	Female	Screen	27/06/91	Normal	
	28	Female	Screen	06/08/91	Normal	
	29	Male	Screen	29/08/91	Normal	
	30	Female	Screen	03/09/91	Normal	
	403	Female	Screen	04/10/91	Normal	
	404	Female	Screen	10/09/91	Abnormal	ASTHMA NOS
	405	Female	Screen	11/11/91	Normal	
	406	Male	Screen	27/11/91	Normal	
	407	Female	Screen	02/12/91	Normal	
	408	Female	Screen	15/01/92	Normal	
	418	Female	Screen	30/01/92	Normal	
	419	Female	Screen	27/04/92	Abnormal	TRACHEA/BRONCHUS DIS NEC

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.
1	1	Female	35	ANAFRANIL	Good	Y	xxx	25/12/90	
	2	Male	49	AMITRIPTYLINE	Good	Y	xxx	11/04/91	
	3	Male	41	LITHIUM TRYPTANOL	Fair Fair		xxx	29/04/91	
	5	Female	57	ANAFRANIL SURMONTIL	Good Good		xxx	08/10/90	
	6	Female	36	PROZAC TRYPTANOL	Good Good	Y Y	xxx	03/91	
	8	Male	49	SINEQUAN	Good		xxx	88	
	9	Female	38	TRYPTANOL	Good		xxx	11/90	
	10	Male	32	NARDIL PROTHIADEN	Poor Poor		xxx	15/09/91	
	11	Female	39	SURMONTIL FLUOXETINE	Fair Good	Y	xxx	07/06/91	
	12	Female	36	TRIMIPRAMINE	Good		xxx	28/09/91	
	412	Male	41	SINEQUAN	Poor		xxx	12/11/91	
	413	Male	51	SINEQUAN TOLYON SURMONTIL	Good Poor Good		xxx	05/12/88	
	414	Female	47	SURMONTIL TOLYON	Good Good		xxx	16/01/92	
	415	Male	40	PROTHIADEN	Good		xxx	24/12/91	

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.
1	421	Male	57	TRIMIPRAMINE	Good		***	06/86	
2/1	49	Female	53	AMAFRANIL	Very poor		***	11/05/91	
2/2	47	Female	35	CHLORIMIPRAMINE	Poor		***	13/03/92	
2/3	48	Female	31	DOSULEPIN	Poor		***	03/04/92	
2/3	36/A	Male	53	MACLANINE			***	26/02/91	
	39	Female	52	CLOMIPRAMINE	Fair		***	31/07/91	
	41	Male	25	FLOVOXAMINE	Fair		***	20/09/91	
2/4	36	Female	57	MACLANINE	Good		***	04/02/91	
2/5	75	Male	50	TRIMIPRAMINE CLOMIPRAMINE MANSERIN	Fair Good Poor		***	02/09/92	
	77	Male	38	IMIPRAMINE FLOXETINE TRIMIPRAMINE	Poor Good Good		***	14/09/92	
	78	Female	51	CLOMIPRAMINE	Very poor		***	23/09/92	
3/1	64	Female	57	SURMONTIL CLEBIAL	Very poor Poor	Y	***	26/02/91	
	139	Male	31	LUDIONIL	Very poor		***	27/08/91	
	140	Male	56	FLOXYFRAL	Fair		***	15/04/91	
	141	Female	40	PROTHLADEN PROZAC	Poor Poor		***	25/09/91	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects taken	Last day of treat.
3/1	143	Female	44	LUDIOMIL	Poor			
	451	Female	57	SURMONTIL	Poor	xxx	xxx	15/01/92
	452	Male	44	LUDIOMIL	Poor	xxx	xxx	16/01/92
	453	Female	55	VIVALAN STABLON	Good Fair	xxx	xxx	91
	454	Male	56	LAROXYL	Poor	xxx	xxx	16/02/92
	455	Female	47	STABLON	Poor	xxx	xxx	04/03/92
3/2	65/A	Female	21	PROZAC SURMONTIL	Poor Poor	xxx	xxx	22/01/91
3/3	67	Male	38	CLONIPRAMINE IMIPRAMINE	Fair Good	xxx	xxx	04/91
	68	Male	45	PROTHIADEN	Good	xxx	xxx	84
	69	Male	34	TRIMIPRAMINE	Fair	xxx	xxx	29/01/92
	70	Male	40	MIANSERIN	Poor			
	71	Female	26	AMOXAPINE	Poor	xxx	xxx	09/04/92
3/4	79	Female	45	HUMORSYL	Poor	xxx	xxx	15/02/90
	81	Female	35	CLONIPRAMINE	Poor	xxx	xxx	14/05/91
	83	Male	49	VILOXAZINE	Poor	xxx	xxx	23/04/91

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PRAMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012a/015
 Listing No.: 6.0
 PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment.	Efficacy	Side effects	Last taken	Last day of treat.
3/4	89	Female	49	PROZAC		Poor		xxx	08/03/92
	90	Male	47	LAROXYL		Poor	Y	xxx	22/04/92
	457	Female	48	CLONIPRAMINE		Very good	Y	xxx	08/91
	458	Female	43	TIAMINEPTINE FLUOXETINE		Fair Good		xxx	15/04/92
	461	Female	45	STABLON		Poor		xxx	31/08/92
4/1	93	Male	18	PRACHABEL		Fair		xxx	02/06/91
	95	Female	42	TINAXEL		Good		xxx	04/87
	119	Female	46	STABLON					
	147	Female	65	VIVALAN ANAFRANIL PROXILADEN		Very poor Poor Good		xxx	09/91
4/2	93/A	Male	48	ANAFRANIL LITHIUM		Fair		xxx xxx	01/10/90
	104	Male	57	LAROXYL		Fair		xxx	30/11/90
4/3	97	Male	42	SURVECTOR		Poor		xxx	10/04/91
	98	Female	58	ANAFRANIL - SLOW RELEASE		Fair		xxx	15/06/91
	100	Female	24	FLOXYFRAL		Poor		xxx	10/09/91
	101	Male	55	PROZAC		Very poor		xxx	25/11/91
4/4	110	Male	64	LUDIOMIL		Poor			

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.0
 PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment:	Efficacy	Side effects	Last taken	Last day of treat.
4/4	111	Male	65	CLOMIPRAMINE		Poor	xxx	xxx	26/06/91
	112	Male	23	MIANSERIN		Very poor	xxx	xxx	04/07/91
	114	Female	62	PROTHIADEN		Poor	xxx	xxx	13/11/91
	179	Female	43	PROZAC		Very poor	xxx	xxx	06/09/92
	180	Male	40	ATBUNIL STABLON		Poor Poor	xxx	xxx	29/09/92
5/1	127	Male	34	FLOXYFRAL		Poor	xxx	xxx	28/05/91
	128	Female	33	PROZAC		Poor			
	131	Female	43	FLUOXAMINE		Poor	xxx	xxx	09/03/92
5/2	125	Male	48	AMINEPTINE FLUOXAMINE		Poor Poor	xxx	xxx	20/01/91
5/3	134	Female	31	PROZAC		Fair	xxx	xxx	23/11/91
6/1	152	Female	56	CLOMIPRAMINE		Very poor	Y	xxx	17/02/92
	153	Male	50	CLEDIAL FLUOXETINE IMIPRAMINE		Poor Good Good	Y	xxx	18/02/91
	155	Male	63	CLOMIPRAMINE		Poor	Y	xxx	01/07/92
	156	Female	41	CLOMIPRAMINE		Fair	xxx	xxx	89
6/2	157	Male	43	VIVALAN		Poor	xxx	xxx	10/04/91

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.
6/2	158	Female	37	QUIYAXON PERTOFRAN		Poor Poor	xxx	xxx	10/11/91
	169	Female	53	FLUOXETINE		Very good	xxx	xxx	06/91
	170	Male	45	VIVALAN		Fair	xxx	xxx	02/90
6/3	163	Male	37	PROZAC		Poor	xxx	xxx	15/05/91
	164	Male	29	STABLON		Poor	xxx	xxx	07/10/91
	165	Female	54	PROZAC		Poor	xxx	xxx	01/10/91
	166	Female	40	MAPROTIline		Poor	xxx	xxx	16/10/91
	167	Female	33	FLUOXETINE CLOMIPRAMINE		Fair Poor	xxx	xxx	01/06/91
	168	Female	34	DOSULEPIN		Poor	xxx	xxx	25/11/91
	505	Female	41	PROZAC		Poor	xxx	xxx	19/11/91
	506	Female	48	PROZAC		Poor	xxx	xxx	16/12/91
	507	Female	34	STABLON FLUOXETAL		Poor Poor	xxx	xxx	06/01/92
	508	Female	52	MEDIFOXAMINE PROZAC		Poor Good	xxx	xxx	28/01/92
	509	Male	27	ANAFRANIL		Fair	xxx	xxx	
	512	Female	23	ANAFRANIL		Good	xxx	xxx	01/12/90

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment.	Efficacy	Side effects taken	Last day of treat.
6/3	515	Female	41	KINUPRIL	Poor	xxx	xxx	28/04/92
7/02	181	Male	36	SAROTEN RETARD	Fair	Y	xxx	17/01/92
	182	Male	57	AMITRIPTYLINE APONAL	Fair Poor	xxx	xxx	10/11/91
	183	Male	51	FLUOXETINE	Very poor	Y	xxx	30/11/91
	184	Female	43	DOXEPIN	Poor	Y	xxx	17/01/92
7/05	205	Male	61	FLUOXETINE	Fair	xxx	xxx	29/12/91
	541	Female	59	FLUOXETINE	Good	xxx	xxx	23/07/91
	542	Male	47	FLUOXETINE		xxx	xxx	02/12/91
	543	Male	50	NOVERIL - SLOW RELEASE	Good	xxx	xxx	17/05/91
	544	Female	56	NOVERIL - SLOW RELEASE	Fair			
	545	Male	55	STANGYL	Fair	xxx	xxx	11/02/92
7/07	530	Female	53	LUDIOMIL	Poor	xxx	xxx	16/02/92
	533	Male	40	DOXEPIN	Poor	xxx	xxx	27/04/92
8	211	Female	41	CLOMIPRAMINE	Good	xxx	xxx	01/02/91
	213	Male	59	CLOMIPRAMINE	Good	xxx	xxx	01/08/91
	214	Female	54	CLOMIPRAMINE	Good	xxx	xxx	

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment.	Efficacy	Side effects	Last taken	Last day of treat.
8	215	Female	46	AMITRIPTYLINE	xxx	Good	xxx	xxx	12/91
	216	Male	46	CLOMIPRAMINE	xxx	Good	xxx	xxx	89
	219	Female	23	FLUVOXAMINE	xxx	Poor	xxx	xxx	02/92
	220	Female	38	CLOMIPRAMINE	xxx	Fair	xxx	xxx	12/90
	224	Female	25	FLUOXETINE	xxx	Good	xxx	xxx	90
	226	Male	58	CLOMIPRAMINE	xxx	Good	xxx	xxx	
	227	Male	64	AMITRIPTYLINE	xxx	Fair	xxx	xxx	91
	229	Female	55	MIANSERIN CLOMIPRAMINE	xxx	Good Fair	xxx	xxx	91
	230	Female	43	MIANSERIN CLOMIPRAMINE	xxx	Fair Good	xxx	xxx	02/92
	231	Male	46	FLUOXETINE	xxx	Good	xxx	xxx	91
	233	Female	52	MIANSERIN	xxx	Good	xxx	xxx	
	234	Female	65	MIANSERIN	xxx	Good	xxx	xxx	91
8/A	236	Female	44	FEVARIIN	xxx	Fair	xxx	xxx	18/09/92
	238	Female	52	FLUVOXAMINE	xxx	Fair	xxx	xxx	18/09/92
	239	Female	62	FEVARIIN	xxx	Good	xxx	xxx	22/09/92
	240	Female	46	CLOMIPRAMINE HYDROCHLORIDE	Y	Good	xxx	xxx	22/09/92

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.0
 PREVIOUS ANTI-DEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.
8/A	554	Male	60	CLOMIPRAMINE HYDROCHLORIDE	Fair	Y	***	22/08/92	
	555	Female	64	AMITRIPTYLINE HYDROCHLORIDE	Good	Y	***	22/09/92	
	556	Male	43	FLUOXETINE	Fair		***	22/09/92	
9	241	Female	43	AMITRIPTYLINE	Poor				
	242	Female	58	LITHIUM	Poor		***	12/01/91	
	243	Female	54	FLUOXAMINE	Poor		***	15/02/91	
	244	Female	56	LITHIUM CHLORIMIPRAMINE AMITRIPTYLINE	Poor Good Good		***	11/02/91	
	246	Female	41	CARBOLITHIUM AMITRIPTYLINE	Poor Good		***	13/02/91	
	247	Female	33	CHLORIMIPRAMINE IMIPRAMINE	Good Good				
	248	Male	37	CHLORIMIPRAMINE	Good				
	249	Female	42	CHLORIMIPRAMINE	Good				
	250	Female	51	AMITRIPTYLINE FLUOXETINE NORTRIPTYLINE	Good Very poor Good		***	07/03/91	
	252	Female	61	NORTRIPTYLINE	Poor				
	253	Female	32	FLUOXAMINE AMITRIPTYLINE AMINEPTINE	Poor Fair Poor		***	28/03/91	

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REBONEXINE - PROTOCOL 20124/015
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment.			Last day of treat.
					Efficacy	Side effects	Last taken	
9	255	Female	24	CLOMIPRAMINE	Poor	xxx	18/04/91	
	256	Female	51	NORTRIPTYLINE	Very poor	xxx	10/05/91	
	11	320	Male	34	TRAZODONE	Good	Y	05/91
		321	Male	45	PROTHIADEN	Fair	xxx	05/91
		322	Female	57	DOXEPIN	Poor	xxx	08/91
12	326	Male	55	LOFEPRAMINE AMITRIPTYLINE MIANSERIN TETRAPRAMINE	Very poor Poor Poor Good	xxx Y	10/91	
	329	Female	40	PROTHIADEN	Poor	xxx	31/03/92	
				PANOXETINE	Poor	Y		
331	Male	54	LOFEPRAMINE	Poor	xxx	07/04/92		
332	Male	64	LOFEPRAMINE	Very poor	xxx	07/05/92		
			FLUOXETINE	Good				
334	Female	36	FLUOXETINE	Poor	Y	17/05/92		
335	Male	33	FLUOXETINE	Poor	xxx	06/05/92		
336	Female	42	IMIPRAMINE LOFEPRAMINE	Poor Poor	xxx	89		
337	Female	25	FLUOXETINE	Very poor	xxx	16/06/92		
			PROTHIADEN	Very poor	Y			
			LOFEPRAMINE	Very poor				
369	Female	50	CHLORIMIPRAMINE	Fair	xxx	14/04/92		

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.0
 PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects taken	Last day of treat.
12	370	Male	60	DESIPRAMINE	Poor	xxx	xxx	23/04/92
	371	Female	50	FLUOXETINE	Fair	xxx	xxx	17/04/92
	375	Male	47	IMIPRAMINE	Poor	xxx	xxx	09/06/92
13	13	Male	44	PROTHIADEN	Poor			
	14	Male	28	TOLYON TOFRANIL PARNATE LITHIUM PROTHIADEN	Fair Poor Poor Poor Poor	xxx	Y	05/91
	15	Female	29	TOFRANIL LITHIUM	Fair Poor	xxx	xxx	16/06/91
	16	Male	52	PARNATE	Fair	xxx	Y	16/11/91
	17	Male	95	LITHIUM	Fair			
	18	Male	51	ANAFRANIL	Fair	xxx	Y	15/06/92
	409	Male	61	AMITRIPTYLINE	Fair	xxx	xxx	11/91
	410	Male	45	AMITRIPTYLINE PARNATE	Good Fair	xxx	Y	07/02/92
	411	Female	40	PARNATE	Fair	xxx	Y	17/03/92
	423	Male	52	PROTHIADEN	Fair	xxx	Y	04/92
14	19	Female	52	TRANALCIPROLINE AMITRIPTYLINE	Very poor Very poor	xxx	xxx	01/04/92

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment:		Last day of treat.
					Efficiency	Side effects taken	
14	20	Female	59	VENLAFAXINE	Very good	***	15/02/90
15	25	Female	60	DOTHIEPIN	Fair	Y	24/03/91
	26	Male	36	VENLAFAXINE	Very good	Y	02/08/90
	27	Female	53	VENLAFAXINE	Very good		
	28	Female	43	VENLAFAXINE	Very good	***	02/08/90
	29	Male	47	DESIPRAMINE DOTHIEPIN	Poor Poor	Y Y	22/08/91
	408	Female	34	CLOMIPRAMINE	Poor	Y	10/01/92

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (B)		Start date	Randomized
1	1	25/12/90	26/12/90	09/04/91	106	10/04/91	Imipramine
	2	11/04/91	12/04/91	14/04/91	4	15/04/91	Reboxetine
	3	29/04/91	30/04/91	05/05/91	7	06/05/91	Imipramine
	4		28/05/91	03/06/91	7	04/06/91	Placebo
	5	08/10/90	20/05/91	11/06/91	23	12/06/91	Reboxetine
	6	03/91	01/04/91	22/05/91	52	23/05/91	Placebo
	7			26/08/91		27/08/91	Reboxetine
	8	88	02/01/88	04/09/91	1343	05/09/91	Placebo
	9	11/90	27/11/90	26/11/91	365	27/11/91	Reboxetine
	10	15/09/91	16/09/91	23/09/91	8	24/09/91	Placebo
	11	07/06/91	04/10/91	09/10/91	6	10/10/91	Imipramine
	12	28/09/91	29/09/91	17/10/91	20	18/10/91	Imipramine
412		12/11/91	13/11/91	12/11/91	0	13/11/91	Reboxetine
413		05/12/88	05/12/91	08/12/91	6	09/12/91	Placebo
414		16/01/92	17/01/92	21/01/92	5	22/01/92	Imipramine
415		24/12/91	25/12/91	13/01/92	21	14/01/92	Imipramine

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (a)	To (b)		Start date	Randomized
1	416		14/01/92	16/01/92	3	17/01/92	Reboxetine
	421	06/86	02/06/86	26/02/92	2097	27/02/92	Imipramine
	422		23/07/92	04/08/92	13	05/08/92	Imipramine
2/1	49	11/05/91	12/05/91	17/05/91	6	18/05/91	Placebo
	50		23/12/91	26/12/91	4	27/12/91	Reboxetine
	51		29/01/92	01/02/92	4	02/02/92	Imipramine
2/2	43		17/04/91	17/04/91		18/04/91	Imipramine
	44		30/06/91	18/07/91	19	19/07/91	Imipramine
	45		90	07/09/91	615	08/09/91	Reboxetine
	46		16/09/91	25/09/91	10	26/09/91	Placebo
	47	13/03/92	14/03/92	23/03/92	11	24/03/92	Placebo
	48	03/04/92	04/04/92	06/04/92	4	07/04/92	Reboxetine
2/3	36/A	26/02/91	27/02/91	06/03/91	9	07/03/91	Imipramine
	37		09/02/91	26/03/91	46	27/03/91	Reboxetine
	38		13/08/91	13/08/91		14/08/91	Placebo
	39	31/07/91	01/08/91	09/08/91	9	10/08/91	Imipramine

(*) if missing date = last day of previous treatment + 1 day
 (a) same as start treatment date - 1 day

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PHARMACIA CRS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (g)		Start date	Randomized
2/3	40		17/10/91	23/10/91	7	24/10/91	Reboxetine
	41	20/09/91	21/09/91	02/10/91	13	03/10/91	Placebo
	42		06/05/92	18/05/92	13	19/05/92	Imipramine
2/4	31		18/03/91	25/03/91	8	26/03/91	Placebo
	32		18/10/91	25/10/91	8	26/10/91	Reboxetine
	33		22/05/91	28/05/91	7	29/05/91	Imipramine
	34			16/04/92		17/04/92	Placebo
	35			14/09/92		15/09/92	Reboxetine
	36	04/02/91	05/02/91	11/02/92	372	12/02/92	Imipramine
2/5	73		28/01/92	06/02/92	10	07/02/92	Placebo
	74		30/04/92	20/06/92	52	21/06/92	Reboxetine
	75	02/09/92	03/09/92	10/09/92	8	11/09/92	Imipramine
	76			14/09/92		15/09/92	Imipramine
	77	14/09/92	15/09/92	21/09/92	7	22/09/92	Placebo
	78	28/09/92	01/10/92	09/10/92	9	10/10/92	Reboxetine
2/6	55		11/06/92		12/06/92	Reboxetine	

(*) if missing date = last day of previous treatment + 1 day
 (g) same as start treatment date - 1 day

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REBOXETINE - PROTOCOL 2012A/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Start date	Treatment Randomized
			From (*)	To (9)			
2/6	56		11/06/92			12/06/92	Reboxetine
	57		04/05/92			05/05/92	Imipramine
	58		17/05/92			18/05/92	Placebo
	59		26/05/92			27/05/92	Placebo
	60		07/05/92	11/05/92	5	12/05/92	Imipramine
3/1	61		04/03/91			05/03/91	Imipramine
	62		15/04/91			16/04/91	Imipramine
	63		12/05/91			13/05/91	Placebo
	64	26/02/91	27/02/91	13/03/91	16	14/03/91	Placebo
	65		15/09/91			16/09/91	Reboxetine
	66		09/06/91			10/06/91	Reboxetine
139		27/08/91	28/08/91	02/09/91	6	03/09/91	Imipramine
140		15/04/91	04/09/91	11/09/91	8	12/09/91	Placebo
141		25/09/91	26/09/91	02/10/91	7	03/10/91	Placebo
142			17/11/91			18/11/91	Imipramine
143		08/04/92	14/04/92		7	15/04/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(9) same as start treatment date - 1 day

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period To (B)		Days	Treatment Randomized	
			From (*)	To (B)		Start date	Treatment
3/1	144		08/06/92			09/06/92	Reboxetine
	451	15/01/92	16/01/92	19/01/92	5	20/01/92	Reboxetine
	452	16/01/92	17/01/92	21/01/92	6	22/01/92	Placebo
	453	91	02/01/91	28/01/92	393	29/01/92	Imipramine
	454	14/02/92	15/02/92	16/02/92	3	17/02/92	Reboxetine
	455	04/03/92	05/03/92	10/03/92	7	11/03/92	Placebo
	456		24/03/92			25/03/92	Imipramine
3/2	65/A	22/01/91	23/01/91	28/01/91	6	29/01/91	Reboxetine
3/3	67	04/91	12/07/91	17/07/91	6	18/07/91	Placebo
	68	84	10/01/92	20/01/92	11	21/01/92	Reboxetine
	69	29/01/92	30/01/92	03/02/92	6	04/02/92	Placebo
	70		08/04/92	14/04/92	7	15/04/92	Imipramine
	71	09/04/92	10/04/92	15/04/92	6	16/04/92	Imipramine
	72		20/07/92	24/07/92	5	25/07/92	Reboxetine
3/4	79	15/02/98	16/02/98	03/05/91	442	04/05/91	Imipramine
	80		31/08/91			01/09/91	Imipramine

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (B)		Start date	Randomized
3/4	81	14/05/91	15/05/91	16/05/91	3	17/05/91	Reboxetine
	82			16/06/91		17/06/91	Placebo
	83	23/04/91	14/06/91	16/06/91	3	17/06/91	Placebo
	84			08/10/91		09/10/91	Reboxetine
	85		25/10/91	28/10/91	4	29/10/91	Imipramine
	86			02/12/91		03/12/91	Imipramine
	87		06/12/91	08/12/91	3	09/12/91	Placebo
	88			22/03/92		23/03/92	Placebo
	89	08/03/92	09/03/92	25/03/92	17	26/03/92	Reboxetine
	90	22/04/92	23/04/92	27/04/92	5	28/04/92	Reboxetine
	457	08/91	18/05/92	21/05/92	4	22/05/92	Placebo
	458	15/04/92	25/04/92	25/05/92	31	26/05/92	Reboxetine
	459		29/05/92	01/06/92	4	02/06/92	Placebo
	460		14/08/92	18/08/92	5	19/08/92	Reboxetine
	461	31/08/92	01/09/92	16/09/92	16	17/09/92	Imipramine
	462			28/09/92		29/09/92	Imipramine

(*) if missing date = last day of previous treatment + 1 day
 (B) same as start treatment date - 1 day

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7

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT PERIOD

Centre	Patient	Last day of previous treatment	From (*)	Wash out period to (B)	Days	Start date	Treatment Randomized
4/1	91		11/10/91			12/10/91	Imipramine
	92		06/08/91			07/08/91	Reboxetine
	93	02/06/91	03/06/91	02/07/91	30	03/07/91	Placebo
	94		04/07/91			05/07/91	Placebo
	95	04/87	02/04/87	02/06/91	1524	03/06/91	Imipramine
	96		03/09/91			04/09/91	Reboxetine
	115		05/05/92			06/05/92	Reboxetine
	116		15/05/92			16/05/92	Imipramine
	117		02/09/91			03/09/91	Imipramine
	118		22/05/92			23/05/92	Reboxetine
	119		10/03/92				Placebo
	120		30/07/92			31/07/92	Placebo
	145		29/09/92			30/09/92	Imipramine
	146		15/09/92			16/09/92	Placebo
	147	09/91	02/09/91	31/08/92	366	01/09/92	Reboxetine
	148		25/09/92			26/09/92	Imipramine

(*) if missing date = last day of previous treatment + 1 day
 (B) same as start treatment date - 1 day

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (B)		Start date	Randomized
4/1	149		29/09/92			30/09/92	Reboxetine
	150		29/09/92			30/09/92	Placebo
4/2	93/A	01/10/90	02/10/90	21/02/91	143	22/02/91	Placebo
	99/A		26/03/91			27/03/91	Placebo
	104	30/11/90	01/12/90	21/05/91	172	22/05/91	Reboxetine
4/3	97	10/04/91	11/04/91	16/04/91	6	17/04/91	Placebo
	98	15/06/91	16/06/91	19/06/91	4	20/06/91	Reboxetine
	99		07/08/91			08/08/91	Placebo
	100	10/09/91	11/09/91	26/11/91	78	27/11/91	Imipramine
	101	25/11/91	26/11/91	16/03/92	112	17/03/92	Imipramine
4/4	109		04/06/91	07/06/91	4	08/06/91	Reboxetine
	110		11/06/91	14/06/91	4	15/06/91	Imipramine
	111	26/06/91	27/06/91	03/07/91	7	04/07/91	Imipramine
	112	04/07/91	05/07/91	09/07/91	5	10/07/91	Placebo
	113		30/08/91			31/08/91	Reboxetine
	114	13/11/91	14/11/91	19/11/91	7	20/11/91	Placebo

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment Randomized
			From (*)	To (B)		
4/4	175		05/02/92	12/02/92	8	Imipramine
	176		10/03/92	13/03/92	4	Placebo
	177		23/04/92	27/04/92	5	Imipramine
	178		01/04/92	27/04/92	27	Reboxetine
5/1	179	06/09/92	07/09/92	10/09/92	4	Placebo
	180	25/09/92	30/09/92	06/10/92	7	Reboxetine
	127	28/05/91	29/05/91	05/06/91	9	Reboxetine
	128		06/06/91	13/06/91	8	Reboxetine
5/2	129		15/12/91	23/12/91	9	Placebo
	130		25/02/92	04/03/92	9	Placebo
5/3	131	09/03/92	10/03/92	20/03/92	11	Imipramine
	132		23/06/92	24/06/92	2	Imipramine
5/2	121		13/12/91	19/12/91	7	Imipramine
	125	20/01/91	21/01/91	27/01/91	8	Reboxetine
5/3	133		28/11/91	28/11/91		Placebo
	134	23/11/91	28/11/91	05/12/91	8	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (B)		Start date	Randomized
5/3	135		30/12/91	09/01/92	11	10/01/92	Imipramine
	136		27/02/92	01/03/92	4	02/03/92	Imipramine
	137		14/05/92	14/05/92		15/05/92	Reboxetine
6/1	138		14/05/92	14/05/92		15/05/92	Placebo
	151		20/01/92	20/01/92		21/01/92	Imipramine
	152	17/02/92	18/02/92	23/02/92	7	24/02/92	Reboxetine
6/2	153	18/02/91	19/02/91	17/03/91	28	18/03/91	Reboxetine
	154		25/03/92	29/03/92	5	30/03/92	Imipramine
	155	01/07/92	02/07/92	07/07/92	7	08/07/92	Placebo
6/2	156	89	01/09/92	07/09/92	7	08/09/92	Placebo
	157	10/04/91	11/04/91	29/04/91	19	30/04/91	Reboxetine
	158	10/11/91	11/11/91	23/11/91	13	24/11/91	Imipramine
6/2	159		05/07/91	13/07/91	9	14/07/91	Imipramine
	160		23/11/91	23/11/91		24/11/91	Placebo
	161		19/02/92	19/02/92		20/02/92	Reboxetine
6/2	162		09/07/91	09/07/91		10/07/91	Placebo

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period To (a)		Days	Treatment Randomized	
			From (*)	To (a)		Start date	Treatment
6/2	169	06/91	09/12/91	25/12/91	17	26/12/91	Imipramine
	170	02/90	17/10/91	31/10/91	15	01/11/91	Placebo
	171			21/07/92		22/07/92	Imipramine
	172			06/07/92		07/07/92	Reboxetine
	173			04/07/92		05/07/92	Placebo
	174			10/05/92		11/05/92	Reboxetine
	163	15/05/91	16/05/91	05/06/91	22	06/06/91	Reboxetine
	164	07/10/91	08/10/91	10/10/91	4	11/10/91	Imipramine
	165	01/10/91	02/10/91	15/10/91	15	16/10/91	Imipramine
	166	16/10/91	17/10/91	24/10/91	9	25/10/91	Reboxetine
6/3	167	01/06/91	02/06/91	17/11/91	170	18/11/91	Placebo
	168	25/11/91	26/11/91	02/12/91	7	03/12/91	Placebo
	505	19/11/91	20/11/91	02/12/91	14	03/12/91	Imipramine
	506	16/12/91	17/12/91	07/01/92	23	08/01/92	Placebo
	507	06/01/92	07/01/92	13/01/92	8	14/01/92	Imipramine
	508	28/01/92	29/01/92	04/02/92	7	05/02/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(a) same as start treatment date - 1 day

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Contro	Patient	Last day of previous treatment	Wash out period		Days	Treatment
			From (*)	To (B)		
6/3	509		18/02/92	23/02/92	6	Placebo
	510		14/02/92	26/02/92	13	Reboxetine
	511			18/05/92		Imipramine
	512	01/12/90	02/12/90	31/05/92	487	Placebo
	513	28/04/92	29/04/92	12/05/92	15	Imipramine
7/02	181	17/01/92	18/01/92	26/01/92	9	Reboxetine
	182	30/11/91	11/11/91	22/11/91	13	Placebo
	183	30/11/91	01/12/91	01/01/92	32	Imipramine
	184	17/01/92	18/01/92	26/01/92	9	Imipramine
	185			09/04/92		Reboxetine
	186			15/04/92		Placebo
	535			14/04/92		Placebo
	536			07/05/92		Reboxetine
7/03	187			17/02/92		Imipramine
	188			24/02/92		Placebo
	189			24/02/92		Placebo

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

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13

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.1
 DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period (G)		Days	Start date	Treatment Randomized
			From (*)	To (G)			
7/03	190		27/02/92			28/02/92	Reboxetine
	191		02/03/92			03/03/92	Imipramine
	192		09/03/92			10/03/92	Reboxetine
	523		05/05/92			06/05/92	Reboxetine
	524		05/05/92			06/05/92	Placebo
	525		05/05/92			06/05/92	Placebo
	526		05/05/92			06/05/92	Reboxetine
	527		18/05/92			19/05/92	Imipramine
	528		18/05/92			19/05/92	Imipramine
	7/04	193		24/01/92			25/01/92
194			24/01/92			25/01/92	Reboxetine
195			24/01/92			25/01/92	Placebo
196			31/01/92			01/02/92	Reboxetine
197			31/01/92			01/02/92	Imipramine
198			31/01/92			01/02/92	Imipramine
199			27/03/92			28/03/92	Imipramine

(*) if missing date = last day of previous treatment + 1 day
 (G) same as start treatment date - 1 day

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14

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (B)		Start date	Randomized
7/04	200		27/03/92			28/03/92	Placebo
	201		27/03/92			28/03/92	Reboxetine
	202		03/04/92			04/04/92	Reboxetine
	203		03/04/92			04/04/92	Placebo
	204		03/04/92			04/04/92	Imipramine
7/05	205	29/12/91	30/12/91		28	27/01/92	Placebo
	206		06/01/92		22	28/01/92	Imipramine
	207		27/01/92			28/01/92	Imipramine
	208		29/01/92			30/01/92	Reboxetine
	209		04/02/92			05/02/92	Placebo
	210		06/02/92			07/02/92	Reboxetine
	541	23/07/91	02/03/92		15	17/03/92	Reboxetine
	542	02/12/91	03/12/91		105	17/03/92	Imipramine
	543	17/05/91	18/05/91		306	18/03/92	Imipramine
	544		03/12/91		112	24/03/92	Placebo
	545	11/02/92	12/02/92		43	25/03/92	Placebo

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

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15

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (B)		Start date	Randomized
7/05	546		24/03/92			25/03/92	Reboxetine
7/07	529		10/02/92	17/02/92	8	18/02/92	Placebo
	530	16/02/92	17/02/92	19/02/92	3	20/02/92	Imipramine
	531		17/02/92	23/02/92	7	24/02/92	Reboxetine
	532		21/04/92	26/04/92	6	27/04/92	Imipramine
	533	27/04/92	28/04/92	03/05/92	7	04/05/92	Reboxetine
	534		12/05/92	14/05/92	3	15/05/92	Placebo
8	211	01/02/91	07/05/91	12/05/91	6	13/05/91	Reboxetine
	212		10/09/91	13/09/91	4	14/09/91	Placebo
	213	01/08/91	18/11/91	21/11/91	4	22/11/91	Imipramine
	214		19/11/91	22/11/91	4	23/11/91	Reboxetine
	215	12/91	14/02/92	17/02/92	4	18/02/92	Placebo
	216	89	23/03/92	26/03/92	4	27/03/92	Imipramine
	217		23/03/92	29/03/92	7	30/03/92	Reboxetine
	218		01/04/92	08/04/92	8	09/04/92	Reboxetine
	219	02/92	03/04/92	10/04/92	8	11/04/92	Placebo

(*) if missing date = last day of previous treatment + 1 day
 (B) same as start treatment date - 1 day

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (%)	To (%)		Start date	Randomized
8	220	12/90	21/04/92	26/04/92	6	27/04/92	Imipramine
	221		24/04/92	27/04/92	4	28/04/92	Imipramine
	222		20/04/92	27/04/92	8	28/04/92	Placebo
	223		04/05/92	10/05/92	7	11/05/92	Imipramine
	224	90	27/08/92	06/09/92	11	07/09/92	Placebo
	225		05/09/92	10/09/92	6	11/09/92	Placebo
	226		15/09/92	22/09/92	8	23/09/92	Reboxetine
	227	91	18/09/92	24/09/92	7	25/09/92	Reboxetine
	228		18/09/92	25/09/92	8	26/09/92	Imipramine
	229	91	24/09/92	29/09/92	6	30/09/92	Imipramine
	230	02/92	24/09/92	27/09/92	4	28/09/92	Reboxetine
	231	91	25/09/92	29/09/92	5	30/09/92	Imipramine
	232		25/09/92	01/10/92	7	02/10/92	Reboxetine
	233		28/09/92	06/10/92	9	07/10/92	Placebo
	234	91	30/09/92	06/10/92	7	07/10/92	Placebo
8/A	235		13/10/92			14/10/92	Placebo

(*) if missing date = last day of previous treatment + 1 day
 (2) same as start treatment date - 1 day

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17

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment Randomized
			From (*)	To (B)		
8/A	236	18/09/92	19/09/92	13/10/92	26	Placebo
	237			13/10/92		Reboxetine
	238	18/09/92	19/09/92	13/10/92	26	Reboxetine
	239	22/09/92	23/09/92	15/10/92	24	Imipramine
	240	22/09/92	23/09/92	15/10/92	24	Imipramine
	553			15/10/92		Placebo
	554	22/08/92	23/08/92	15/10/92	55	Reboxetine
	555	22/09/92	23/09/92	15/10/92	24	Reboxetine
	556	22/09/92	23/09/92	15/10/92	24	Imipramine
9	241		04/02/91	06/02/91	3	Placebo
	242	12/01/91	13/02/91	17/02/91	5	Reboxetine
	243	15/02/91	16/02/91	19/02/91	4	Reboxetine
	244	11/02/91	12/02/91	18/02/91	8	Imipramine
	245		17/02/91	21/02/91	5	Imipramine
	246	13/02/91	18/02/91	21/02/91	4	Placebo
	247		21/02/91	24/02/91	4	Placebo

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

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18

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (3)		Start date	Randomized
9	248		04/03/91	06/03/91	3	07/03/91	Placebo
	249		04/03/91	07/03/91	4	08/03/91	Reboxetine
	250	07/03/91	08/03/91	11/03/91	5	12/03/91	Imipramine
	251		13/03/91	19/03/91	7	20/03/91	Imipramine
	252		28/03/91	01/04/91	5	02/04/91	Reboxetine
	253	28/03/91	29/03/91	01/04/91	4	02/04/91	Reboxetine
	254		05/04/91	08/04/91	4	09/04/91	Imipramine
	255	18/04/91	19/04/91	12/05/91	24	13/05/91	Reboxetine
	256	10/05/91	11/05/91	26/05/91	17	27/05/91	Imipramine
	257		21/06/91	24/06/91	4	25/06/91	Placebo
11	258		25/06/91	30/06/91	6	01/07/91	Placebo
	319		01/08/91	01/08/91		02/08/91	Placebo
	320	05/91	02/05/91	16/08/91	108	17/08/91	Imipramine
	321	05/91	02/05/91	05/09/91	128	06/09/91	Placebo
	322	08/91	02/08/91	26/09/91	57	27/09/91	Reboxetine
	323		14/11/91	14/11/91		15/11/91	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(3) same as start treatment date - 1 day

9550082

19

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PHARMACIA CNS 88D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (8)		Start date	Randomized
11	324		05/12/91			06/12/91	Imipramine
	325		12/12/91			13/12/91	Reboxetine
	326	10/91	02/10/91	15/01/92	107	16/01/92	Placebo
	327			29/01/92		30/01/92	Imipramine
	328			30/01/92		31/01/92	Imipramine
	329	31/03/92	01/04/92	09/04/92	9	10/04/92	Placebo
	330			08/04/92		09/04/92	Reboxetine
	331	07/04/92	08/04/92	16/04/92	9	17/04/92	Imipramine
	332	07/05/92	08/05/92	18/05/92	11	19/05/92	Reboxetine
	333			26/05/92		27/05/92	Placebo
	334	17/05/92	18/05/92	28/05/92	12	29/05/92	Reboxetine
12	335	06/05/92	07/05/92	02/06/92	27	03/06/92	Placebo
	336	89	02/01/89	17/06/92	1264	18/06/92	Imipramine
	337	16/06/92	17/06/92	01/07/92	16	02/07/92	Reboxetine
	338			22/07/92		23/07/92	Imipramine
	367		15/12/91	19/12/91	5	20/12/91	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(8) same as start treatment date - 1 day

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20

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (B)		Start date	Randomized
12	368		19/12/91	23/12/91	5	24/12/91	Placebo
	369	14/04/92	17/04/92	22/04/92	6	23/04/92	Imipramine
	370	23/04/92	24/04/92	28/04/92	6	29/04/92	Placebo
	371	17/04/92	18/04/92	30/04/92	14	01/05/92	Imipramine
	372		28/05/92	01/06/92	5	02/06/92	Reboxetine
	373		03/06/92	04/06/92	2	05/06/92	Reboxetine
	374		03/06/92	08/06/92	6	09/06/92	Placebo
	375	09/06/92	12/06/92	16/06/92	5	17/06/92	Imipramine
13	13		03/04/91	12/04/91	10	13/04/91	Placebo
	14		02/05/91	01/07/91	62	02/07/91	Placebo
	15	16/06/91	01/07/91	04/07/91	4	05/07/91	Imipramine
	16	16/11/91	17/11/91	02/12/91	16	03/12/91	Imipramine
	17		20/04/92	20/05/92	31	21/05/92	Reboxetine
	18	15/06/92	16/06/92	23/06/92	9	24/06/92	Reboxetine
	409	11/91	23/11/91	09/12/91	17	10/12/91	Reboxetine
	410	07/02/92	08/02/92	13/02/92	7	14/02/92	Placebo

(*) if missing date = last day of previous treatment + 1 day
 (B) same as start treatment date - 1 day

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21

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period To (a)		Days	Treatment Randomized	
			From (*)	To (a)		Start date	Treatment
13	411	17/03/92	18/03/92	27/03/92	11	28/03/92	Imipramine
	423	04/92	02/04/92	13/09/92	166	14/09/92	Placebo
14	19	01/04/92	02/04/92	09/04/92	9	10/04/92	Reboxetine
	20	15/02/90	16/02/90	28/04/92	804	29/04/92	Imipramine
15	21		15/07/92	19/07/92	5	20/07/92	Imipramine
	25	24/03/91	25/03/91	17/06/91	85	18/06/91	Reboxetine
26	26	02/08/90	03/08/90	19/06/91	321	20/06/91	Placebo
	27		28/11/90	01/07/91	216	02/07/91	Imipramine
28	28	02/08/90	03/08/90	07/08/91	370	08/08/91	Reboxetine
	29	22/08/91	23/08/91	28/08/91	7	29/08/91	Placebo
30	30			02/09/91		03/09/91	Imipramine
	403			03/10/91		04/10/91	Imipramine
404	404			07/10/91		08/10/91	Reboxetine
	405			10/11/91		11/11/91	Placebo
406	406			26/11/91		27/11/91	Imipramine
	407			02/12/91		03/12/91	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(a) same as start treatment date - 1 day

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22

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period		Days	Treatment	
			From (*)	To (‡)		Start date	Randomized
15	408	10/01/92	11/01/92	19/01/92	9	20/01/92	Placebo
	418			29/01/92		30/01/92	Placebo
	419			27/04/92		28/04/92	Placebo

915

(*) if missing date = last day of previous treatment + 1 day
(‡) same as start treatment date - 1 day

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R0550082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 1

	Patient												
	1	2	3	4	5	6	7	8	9	10	11	12	412
	Fem.	Male	Male	Male	Fem.	Fem.	Fem.	Male	Fem.	Male	Fem.	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS 0550082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 1

	Patient					
	413	414	415	416	421	422
	Male	Fem.	Male	Fem.	Male	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 9850082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2/1

	Patient		
	49	50	51
	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?			
Aged between 18 and 65 years inclusive	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?			
Dysthymia, Cyclothymia	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES
Pregnancy	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES
MNST < 22	YES	YES	YES
High risk of suicide	YES	YES	YES

PHARMACIA CNS 9600082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2/2

	Patient					
	43	44	45	46	47	48
	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during ...	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MNST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 9650082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2/3

	Patient						
	36/A	37	38	39	40	41	42
	Male	Fem.	Male	Fem.	Fem.	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?							
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?							
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	N/A	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	N/A	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES

PHARNACIA CNS 050082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2/4

	Patient					
	31	32	33	34	35	36
	Male	Male	Male	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 00082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2/5

	Patient					
	73	74	75	76	77	78
	Male	Male	Male	Fem.	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
NHST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CN0540082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2/6

	Patient					
	55	56	57	58	59	60
	Fem.	Fem.	Fem.	Fem.	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiently	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 140082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 3/1

	Patient												
	61	62	63	64	65	66	139	140	141	142	143	144	451
	Male	Fem.	Male	Fem.	Male	Male	Male	Male	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS 9540082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 3/1

	Patient				
	452	453	454	455	456
	Male	Fem.	Male	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?					
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?					
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

PHARNACIA CNS 540082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 3/2

	Pati- ent
	65/A
	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?	
Aged between 18 and 65 years inclusive	YES
Affected by acute episodes of DSM-III-R.	YES
With a total score of 22 of above 21HAMD	YES
Able and willing to give Informed Cons..	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?	
Dysthymia, Cyclothymia	YES
History of DSM-III-R, associated to	YES
Pregnancy	YES
Refusal of contraceptive use during	YES
Clinically significant hematopoietic ...	YES
Clinically significant lab values abnor.	YES
Current evidence of urinary retention	YES
Current evidence of glaucoma	YES
Clinically significant physical abnormal.	YES
Participation in a clinical trial with .	YES
Evidence of substance use disorder	YES
Chronic respiratory insufficiency	YES
History of drug hypersensitivity	YES
Any history of seizures or brain injury	YES
Any other important clinical illness ...	YES
ECT in the previous 6 months	YES
MMST < 22	YES
High risk of suicide	YES

PHARMACIA CNS 050082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 3/3

	Patient					
	67	68	69	70	71	72
	Male	Male	Male	Male	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to ...	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during ...	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 960082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 3/4

	Patient												
	79	80	81	82	83	84	85	86	87	88	89	90	457
	Fem.	Male	Fem.	Male	Male	Fem.	Fem.	Male	Fem.	Male	Fem.	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS 9680082
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 7.0
 INCLUSION / EXCLUSION CRITERIA
 Centre: 3/4

	Patient				
	458	459	460	461	462
	Fem.	Fem.	Male	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?					
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?					
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

PHARMACIA CNS 9650082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 4/1

	Patient												
	91	92	93	94	95	96	115	116	117	118	119	120	145
	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21NAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS 9980082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 4/1

	Patient				
	146	147	148	149	150
	Fem.	Fem.	Fem.	Male	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?					
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?					
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

PHARMACIA CNS 990082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 4/2

	Patient		
	93/A	99/A	104
	Male	Male	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?			
Aged between 18 and 65 years inclusive	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?			
Dysthymia, Cyclothymia	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES
Pregnancy	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES
MHST < 22	YES	YES	YES
High risk of suicide	YES	YES	YES

PHARMACIA CNS 9540082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 4/3

	Patient				
	97	98	99	100	101
	Male	Fem.	Fem.	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?					
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?					
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

PHARMACIA CNS 0082
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 7.0
 INCLUSION / EXCLUSION CRITERIA
 Centre: 4/4

	Patient											
	109	110	111	112	113	114	175	176	177	178	179	180
	Fem.	Male	Male	Male	Male	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?												
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?												
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 050082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 5/1

	Patient					
	127	128	129	130	131	132
	Male	Fem.	Male	Male	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 960082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 5/2

	Patient	
	121	125
	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?		
Aged between 18 and 65 years inclusive	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES
With a total score of 22 or above 21HAMD	YES	YES
Able and willing to give Informed Cons..	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?		
Dysthymia, Cyclothymia	YES	YES
History of DSM-III-R, associated to	YES	YES
Pregnancy	YES	YES
Refusal of contraceptive use during	YES	YES
Clinically significant hematopoietic ...	YES	YES
Clinically significant lab values abnor.	YES	YES
Current evidence of urinary retention	YES	YES
Current evidence of glaucoma	YES	YES
Clinically significant physical abnormal.	YES	YES
Participation in a clinical trial with .	YES	YES
Evidence of substance use disorder	YES	YES
Chronic respiratory insufficiency	YES	YES
History of drug hypersensitivity	YES	YES
Any history of seizures or brain injury	YES	YES
Any other important clinical illness ...	YES	YES
ECT in the previous 6 months	YES	YES
MMST < 22	YES	YES
High risk of suicide	YES	YES

PHARMACIA CNS 980082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 5/3

	Patient					
	133	134	135	136	137	138
	Male	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	NO
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 9150082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 6/1

	Patient					
	151	152	153	154	155	156
	Male	Fem.	Male	Fem.	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 09050082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 6/2

	Patient											
	157	158	159	160	161	162	169	170	171	172	173	174
	Male	Fem.	Male	Male	Fem.	Male	Fem.	Male	Fem.	Fem.	Male	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?												
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?												
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 900082
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 7.0
 INCLUSION / EXCLUSION CRITERIA
 Centre: 6/3

	Patient												
	163	164	165	166	167	168	505	506	507	508	509	510	511
	Male	Male	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 24HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CN9500082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 6/3

	Patient	
	512	513
	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?		
Aged between 18 and 65 years inclusive	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES
With a total score of 22 or above 21HAMD	YES	YES
Able and willing to give Informed Cons..	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?		
Dysthymia, Cyclothymia	YES	YES
History of DSM-III-R, associated to	YES	YES
Pregnancy	YES	YES
Refusal of contraceptive use during	YES	YES
Clinically significant hematopoietic ...	YES	YES
Clinically significant lab values abnor.	YES	YES
Current evidence of urinary retention	YES	YES
Current evidence of glaucoma	YES	YES
Clinically significant physical abnormal.	YES	YES
Participation in a clinical trial with .	YES	YES
Evidence of substance use disorder	YES	YES
Chronic respiratory insufficiency	YES	YES
History of drug hypersensitivity	YES	YES
Any history of seizures or brain injury	YES	YES
Any other important clinical illness ...	YES	YES
ECT in the previous 6 months	YES	YES
MMST < 22	YES	YES
High risk of suicide	YES	YES

PHARMACIA CNS 950082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 7/02

	Patient							
	181	182	183	184	185	186	535	536
	Male	Male	Male	Fem.	Male	Male	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?								
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAND	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?								
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 0082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 7/03

	Patient											
	187	188	189	190	191	192	523	524	525	526	527	528
	Fem.	Male	Male	Male	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?												
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?												
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 9650082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 7/04

	Patient											
	193	194	195	196	197	198	199	200	201	202	203	204
	Fem.	Male	Fem.	Fem.	Male	Fem.	Male	Male	Fem.	Male	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?												
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAND	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?												
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 090082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 7/05

	Patient											
	205	206	207	208	209	210	541	542	543	544	545	546
	Male	Fem.	Fem.	Male	Male	Male	Fem.	Male	Male	Fem.	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?												
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?												
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CN950082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 7/07

	Patient					
	529	530	531	532	533	534
	Fem.	Fem.	Fem.	Fem.	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAND	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CN980082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 8

	Patient												
	211	212	213	214	215	216	217	218	219	220	221	222	223
	Fem.	Fem.	Male	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CN0540082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 8

	Patient										
	224	225	226	227	228	229	230	231	232	233	234
	Fem.	Male	Male	Male	Male	Fem.	Fem.	Male	Male	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?											
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?											
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 550082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 8/A

	Patient									
	235	236	237	238	239	240	553	554	555	556
	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?										
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?										
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 9550082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 9

	Patient												
	241	242	243	244	245	246	247	248	249	250	251	252	253
	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	N/A	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	N/A	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS 950082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 9

	Patient				
	254	255	256	257	258
	Fem.	Fem.	Fem.	Male	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?					
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?					
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

PHARMACIA CN0550082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 11

	Patient												
	319	320	321	322	323	324	325	326	327	328	329	330	331
	Male	Male	Male	Fem.	Male	Male	Male	Male	Male	Fem.	Fem.	Male	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 2HAND	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CN 9550082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 11

	Patient						
	332	333	334	335	336	337	338
	Male	Male	Fem.	Male	Fem.	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?							
Agod between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 24HAMD	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?							
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CNS 050082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 12

	Patient								
	367	368	369	370	371	372	373	374	375
	Fem.	Fem.	Fem.	Male	Fem.	Male	Male	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?									
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?									
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	N/A	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	N/A	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CN 9550082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 13

	Patient									
	13	14	15	16	17	18	409	410	411	423
	Male	Male	Fem.	Male	Male	Male	Male	Male	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?										
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?										
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CN050082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14

	Patient		
	19	20	21
	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?			
Aged between 18 and 65 years inclusive	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES
With a total score of 22 or above 21HAMD	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?			
Dysthymia, Cyclothymia	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES
Pregnancy	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES
Clinically significant physical abnormal.	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES
Chronic respiratory insufficiency	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES
Any history of seizures or brain injury	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES
MMST < 22	YES	YES	YES
High risk of suicide	YES	YES	YES

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CN950082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 15

	Patient													
	25	26	27	28	29	30	403	404	405	406	407	408	418	
	Fem.	Male	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	
ARE THE FOLLOWING CONDITIONS PRESENT ?														
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
ARE THE FOLLOWING CONDITIONS ABSENT ?														
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Chronic respiratory insufficiency	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Any history of seizures or brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
MMST < 22	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	

(CONTINUED)

PHARMACIA CNS 050082

REBOXETINE - PROTOCOL 20124/015
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 15

	Pati-ent
	419
	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?	
Aged between 18 and 65 years inclusive	YES
Affected by acute episodes of DSM-III-R.	YES
With a total score of 22 or above 21HAMD	YES
Able and willing to give Informed Cons..	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?	
Dysthymia, Cyclothymia	YES
History of DSM-III-R, associated to	YES
Pregnancy	YES
Refusal of contraceptive use during	YES
Clinically significant hematopoietic ...	YES
Clinically significant lab values abnor.	YES
Current evidence of urinary retention	YES
Current evidence of glaucoma	YES
Clinically significant physical abnormal.	YES
Participation in a clinical trial with .	YES
Evidence of substance use disorder	YES
Chronic respiratory insufficiency	YES
History of drug hypersensitivity	YES
Any history of seizures or brain injury	YES
Any other important clinical illness ...	YES
ECT in the previous 6 months	YES
MMST < 22	YES
High risk of suicide	YES

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1

9550082

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
1	1	Female	Imipramine	YES	XYLANTA	17/04/91	Day 42	22/05/91(*)	Day 42
	2	Male	Reboxetine	YES	NORMISON	10/04/91	Screen	24/04/91	Day 21
	4	Male	Placebo	YES	NORMISON	15/04/91	Day 21	23/05/91	Day 42
					MOCADON	02/06/91	Screen	04/06/91	Screen
	5	Female	Reboxetine	NO	NORMISON	04/06/91	Screen	06/06/91	Day 7
					ANXIL	19/06/91	Day 14	26/06/91	Day 14
					NORMISON	12/06/91	Screen	02/07/91(*)	Day 21
	6	Female	Placebo	NO	NORMISON	23/05/91	Screen	05/07/91(*)	Day 28
					PANADOL	28/05/91	Day 7	05/07/91(*)	Day 7
	7	Female	Reboxetine	YES	NORMISON	27/08/91	Day 7	20/09/91	Day 21
	8	Male	Placebo	YES	ASPIRINE	20/09/91	Day 21	21/09/91	Day 21
	9	Female	Reboxetine	YES	NORMISON	05/09/91	Screen	19/10/91(*)	Day 42
					NORMISON	27/11/91	Screen	06/01/92(*)	Day 42
	10	Male	Placebo	YES	ASPRO	21/10/91	Day 28	21/10/91	Day 28
					VALIUM	15/10/91	Day 21	15/10/91	Day 21
	11	Female	Imipramine	NO	NORMISON	09/91	Day 7	10/10/91	Screen

(*) - start date missing = screening date
(*) - end date missing = last dose taken date

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2

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
1	12	Female	Imipramine	YES	ASPIRIN 'BAYER'	14/11/91	Day 28	14/11/91	Day 28
	412	Male	Reboxetine	YES	NORMISON	12/11/91	Screen	14/12/91	Day 42
	413	Male	Placebo	YES	NAPROSYN	06/89 24/12/91	Screen Day 21	03/12/91 20/01/92(*)	Screen Day 42
	414	Female	Imipramine	NO	NICOTINIC ACID	03/12/91(§)	Screen	03/12/91	Screen
	415	Male	Imipramine	YES	NORMISON	21/01/92	Day 7	29/01/92(*)	Day 14
					NORMISON	21/01/92	Day 7	29/01/92	Day 21
					SENA	19/02/92	Day 35	19/02/92	Day 35
	416	Female	Reboxetine	NO	NORMISON	24/01/92	Day 7	30/01/92	Day 14
	421	Male	Imipramine	YES	ASPIRINE	26/02/92(§)	Screen	09/04/92(*)	Day 42
					SEKOKOT	26/02/92(§)	Day 42	09/04/92(*)	Day 42
					TEHAZEPAN	27/02/92	Screen	09/04/92(*)	Day 35
	422	Male	Imipramine	YES	ORUDIS	04/08/92(§)	Screen	04/08/92	Screen
2/1	49	Female	Placebo	YES	NOCTEC	14/05/91	Screen	28/06/91(*)	Day 42
	50	Female	Reboxetine	YES	EFFERALGAN	29/12/91	Day 7	31/12/91	Day 7
					NOCTEC	23/12/91	Screen	05/02/92	Day 42
					VENTOLINE	22/01/92 27/01/92	Day 28 Day 35	22/01/92 27/01/92	Day 28 Day 35

(§) - start date missing = screening date
(*) - end date missing = last dose taken date

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3

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 8.0
 CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
2/1	50	Female	Reboxetine	YES	VENTOLINE	03/02/92	Day 42	03/02/92	Day 42
	51	Female	Imipramine	YES	DI-ANTALVIC	21/02/92	Day 21	04/03/92	Day 35
					NOCTEC	28/01/92	Screen	15/03/92(*)	Day 42
					SPAGULAX	21/02/92	Day 21	29/02/92	Day 28
2/2	43	Female	Imipramine	NO	ASPRO	02/05/91	Day 28	02/05/91	Day 28
					NOCTEC	01/05/91	Day 14	01/05/91	Day 14
						12/05/91	Day 28	13/05/91	Day 28
						15/05/91	Day 35	15/05/91	Day 35
					VISCERALGINE	02/05/91	Day 28	02/05/91	Day 28
9	44	Female	Imipramine	YES	ADEPAL	19/07/91	Day 7	29/08/91(*)	Day 42
61					ARGININE	20/07/91	Day 7	25/07/91	Day 7
					DIANE	08/90	Screen	19/07/91	Screen
					EFFERALGAN	01/90	Screen	19/07/91	Screen
					FERROGRAD C	26/08/91	Day 42	29/08/91(*)	Day 42
					NOCTEC	07/07/91	Day 21	07/07/91	Day 21
						25/07/91	Day 14	25/07/91	Day 14
						11/08/91	Day 28	11/08/91	Day 28
						22/08/91	Day 42	22/08/91	Day 42
						25/08/91	Day 42	25/08/91	Day 42
	45	Female	Reboxetine	YES	ADEPAL	10/09/91	Day 7	20/10/91(*)	Day 42

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4

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
2/2	45	Female	Reboxetine	YES	AGAR	04/10/91	Day 28	04/10/91	Day 28
					ALKA-SELYZER	16/09/91 24/09/91	Day 14 Day 21	16/09/91 24/09/91	Day 14 Day 21
					EUPHYTOSE	05/10/91	Day 28	05/10/91	Day 28
					GELATIN	04/10/91	Day 28	04/10/91	Day 28
					HISTAGLOBINE	19/08/91	Screen	04/10/91	Screen
					HISTAMINE	01/10/91 05/10/91	Day 28 Day 28	01/10/91 05/10/91	Day 28 Day 28
					HIFOSTAMINE	09/08/91	Screen	09/10/91	Screen
					KALIN	04/10/91	Day 28	04/10/91	Day 28
					NOCTEC	09/09/91 11/09/91 23/09/91	Day 7 Day 7 Day 21	09/09/91 11/09/91 26/09/91	Day 7 Day 7 Day 21
						01/10/91 09/10/91 15/10/91	Day 28 Day 35 Day 42	01/10/91 09/10/91 16/10/91	Day 28 Day 35 Day 42
	46	Female	Placebo	NO	NOCTEC	26/09/91 17/10/91	Day 7 Day 28	15/10/91 23/10/91	Day 21 Day 28
	47	Female	Placebo	YES	NOCTEC	13/03/92	Screen	17/04/92	Day 28
	48	Female	Reboxetine	YES	NOCTEC	03/04/92	Screen	28/04/92	Day 28
2/3	36/A	Male	Imipramine	YES	ODDIBIL	23/03/91	Day 21	17/04/91(*)	Day 42
	37	Female	Reboxetine	YES	NOCTEC	18/03/91	Screen	07/05/91(*)	Day 42

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 8.0
 CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
2/3	39	Female	Imipramine	YES	NOCTEC	01/08/91	Screen	20/09/91	Day 42
	40	Female	Reboxetine	YES	DIHYDROERGOTAMIN	31/10/91	Day 14	04/12/91(*)	Day 42
	42	Female	Imipramine	YES	VITAMIN B 1-6-12	17/10/91	Screen	04/12/91(*)	Day 42
					ASPIRINE	17/06/92	Day 35	20/06/92	Day 42
					CEFUROXIME	17/06/92	Day 35	30/06/92(*)	Day 42
					CIFLOX	04/05/92	Screen	11/05/92	Screen
					NOROXIN	15/05/92	Screen	15/06/92	Day 28
2/4	31	Male	Placebo	YES	NOCTEC	25/03/91	Day 7	05/05/91(*)	Day 42
	32	Male	Reboxetine	YES	DICLOXINE	87	Screen	06/12/91(*)	Day 42
					IBUPROFEN	87	Screen	06/12/91(*)	Day 42
					LASILIX	87	Screen	06/12/91(*)	Day 42
					NOCTEC	18/10/91	Screen	06/12/91(*)	Day 42
					POTASSIUM	87	Screen	06/12/91(*)	Day 42
	33	Male	Imipramine	YES	NOCTEC	22/05/91	Screen	10/07/91(*)	Day 42
	34	Female	Placebo	YES	HEPT-A-MYL	10/04/92(\$)	Screen	28/05/92(*)	Day 42
					NOCTEC	17/04/92	Day 7	28/05/92(*)	Day 42

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6

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
2/4	34	Female	Placebo	YES	PRAXILENE	04/88	Screen	28/05/92(*)	Day 42
	35	Female	Reboxetine	YES	AMPECYCLAL	07/92	Screen	26/10/92(*)	Day 42
	36	Female	Imipramine	YES	CHLORAL HYDRATE	12/02/92	Day 7	17/03/92	Day 35
					DIFFU K	12/02/92 28/02/92	Day 35 Day 21	17/02/92 24/03/92(*)	Day 35 Day 42
					INSULIN MONOTARD	87	Screen	24/03/92(*)	Day 42
					LOXEN	90	Screen	24/03/92(*)	Day 42
2/5	73	Male	Placebo	YES	ATARAX	27/01/92	Screen	03/02/92	Screen
					CHLORAL HYDRATE	07/02/92	Day 7	20/03/92(*)	Day 42
	74	Male	Reboxetine	YES	NAFTIDROFURYL DXALATE	89	Screen	01/08/92(*)	Day 42
	75	Male	Imipramine	YES	CHLORAL HYDRATE	03/09/92	Day 7	02/10/92	Day 28
					HYDROXYZINE	03/10/92	Day 28	06/10/92	Day 28
					LEVONEPROMAZINE	03/10/92	Day 28	06/10/92	Day 28
	76	Female	Imipramine	YES	CHLORAL HYDRATE	19/09/92	Day 21	26/10/92(*)	Day 42
					DIHYDROERGOTAMIN	24/09/92	Day 14	28/09/92	Day 14
	77	Male	Placebo	YES	LEVONEPROMAZINE	23/06/92	Screen	17/09/92	Screen

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7

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 8.0
 CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
2/6	55	Female	Reboxetine	YES	CHLORAL HYDRATE	12/06/92	Screen	23/07/92(*)	Day 42
	56	Female	Reboxetine	YES	CHLORAL HYDRATE	12/06/92	Screen	23/07/92(*)	Day 42
	57	Female	Imipramine	YES	CHLORAL HYDRATE	05/05/92	Screen	15/06/92(*)	Day 42
	58	Female	Placebo	YES	CHLORAL HYDRATE	18/05/92	Screen	29/06/92(*)	Day 42
	59	Male	Placebo	NO	CHLORAL HYDRATE	27/05/92	Screen	23/06/92(*)	Day 28
	60	Female	Imipramine	YES	CHLORAL HYDRATE	07/06/92	Screen	22/06/92(*)	Day 42
3/1	144	Female	Reboxetine	YES	HEPT-A-NYL	15/06/92	Day 14	22/07/92(*)	Day 42
	451	Female	Reboxetine	NO	DUPHALAC	28/01/92	Day 7	01/02/92(*)	Day 14
49					MICROLAX	29/01/92	Day 14	29/01/92	Day 14
50					ALDOMET	88	Screen	10/03/92(*)	Day 42
51					DIANICRON	22/01/92(\$)	Screen	10/03/92(*)	Day 42
					DUPHALAC	31/01/92	Day 14	10/03/92(*)	Day 42
					LIPANTHVL	88	Screen	10/03/92(*)	Day 42
	456	Female	Imipramine	NO	DUPHALAC	01/04/92	Day 7	03/04/92	Day 14
					HEPT-A-NYL	02/92	Screen	03/04/92(*)	Day 14
					NATSEIDINE	02/92	Screen	03/04/92(*)	Day 14

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8

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
3/2	65/A	Female	Reboxetine	YES	NOCTEC	29/01/91	Day 7	11/03/91(*)	Day 42
3/3	67	Male	Placebo	YES	CHLORAL HYDRATE	12/07/91	Screen	24/07/91	Day 7
69		Male	Placebo	YES	NOCTEC	19/08/91	Day 35	28/08/91(*)	Day 42
	69	Male	Placebo	YES	NOCTEC	29/01/92	Screen	16/03/92(*)	Day 42
	70	Male	Imipramine	YES	TERCIAN	29/02/92	Day 28	02/03/92	Day 28
	70	Male	Imipramine	YES	INDOMETACIN	08/04/92	Screen	15/04/92	Day 7
966					KETOPROFEN	15/04/92	Day 7	26/05/92(*)	Day 42
	71	Female	Imipramine	YES	NOCTEC	08/04/92	Screen	26/05/92(*)	Day 42
	71	Female	Imipramine	YES	PROPRANOLOL	10/02/92	Screen	27/05/92(*)	Day 42
	72	Male	Reboxetine	YES	CHLORAL HYDRATE	21/07/92	Screen	01/08/92	Day 14
3/4	79	Female	Imipramine	YES	CHLORAL HYDRATE	04/05/91	Day 7	11/05/91	Day 7
	81	Female	Reboxetine	YES	CHLORAL HYDRATE	14/05/91	Day 7	22/05/91	Day 7
	82	Male	Placebo	YES	ETHINYL ESTRADIOL M/NORGE	14/05/91(\$)	Screen	27/06/91(*)	Day 42
	83	Male	Placebo	NO	CHLORAL HYDRATE	14/06/91	Screen	01/07/91	Day 21
	83	Male	Placebo	NO	BECLONASON	90	Screen	24/06/91(*)	Day 7
	83	Male	Placebo	NO	THEOPHYLLINE	90	Screen	24/06/91(*)	Day 7

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
3/4	84	Female	Reboxetine	YES	ETHINYLESTRADIOL	86	Screen	23/11/91(*)	Day 42
					NORGESTREL	86	Screen	23/11/91(*)	Day 42
	85	Female	Imipramine	YES	CHLORAL HYDRATE	25/10/91	Screen	06/12/91	Day 42
	87	Female	Placebo	YES	ALINAN	06/01/92	Day 35	18/01/92	Day 42
					CHLORAL HYDRATE	06/12/91	Screen	17/12/91	Day 14
					MINIPHAZE	06/12/91	Screen	19/01/92(*)	Day 42
					THEOSTAT	09/91	Screen	19/01/92(*)	Day 42
	89	Female	Reboxetine	YES	CHLORAL HYDRATE	02/04/92	Day 14	06/05/92(*)	Day 42
	457	Female	Placebo	NO	CHLORAL HYDRATE	29/05/92	Day 14	11/06/92(*)	Day 21
	458	Female	Reboxetine	NO	PARACETAMOL	04/06/92	Day 14	08/06/92	Day 14
					PRIMPERAN	02/06/92	Day 14	09/06/92(*)	Day 14
	459	Female	Placebo	YES	COLCHICINE	24/06/92	Day 28	13/07/92(*)	Day 42
					DAFALGAN	24/06/92	Day 28	05/07/92	Day 35
					DUSPATALIN	24/06/92	Day 28	13/07/92(*)	Day 42
					HYDROGESTERONE	29/05/92(\$)	Screen	13/07/92(*)	Day 42
					GAVISCAN	91	Screen	13/07/92(*)	Day 42

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10

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 6.0
CONCOMITANT DRUGS

9550082

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
3/4	459	Female	Placebo	YES	DESTADIOL	91	Day 42	13/07/92(*)	Screen
					PARACETAMOL	18/06/92	Day 21	22/06/92	Day 21
4/1	92	Female	Reboxetine	YES	SULFARLER	10/06/92	Day 14	13/07/92(*)	Day 42
	96	Female	Reboxetine	YES	CLAROXYL	13/09/91	Day 42	23/09/91	Day 42
	117	Female	Imipramine	YES	ISONERIDE	10/09/91	Day 21	25/09/91	Day 21
	146	Female	Placebo	YES	LEVOTHYROX	58	Screen	14/10/91(*)	Day 42
	148	Female	Imipramine	YES	LOPRIL	91	Screen	27/10/92(*)	Day 42
4/3	99	Female	Placebo	NO	AVLOCARDYL	87	Screen	06/11/92(*)	Day 42
4/4	109	Female	Reboxetine	YES	MAALOX	14/08/91	Day 14	15/08/91(*)	Day 14
	110	Male	Imipramine	YES	CHLORAL HYDRATE	03/06/91	Screen	19/07/91(*)	Day 42
	111	Male	Imipramine	YES	CHLORAL HYDRATE	03/06/91	Screen	26/07/91(*)	Day 42
	112	Male	Placebo	YES	CHLORAL HYDRATE	27/06/91	Screen	14/08/91(*)	Day 42
	113	Male	Reboxetine	YES	CHLORAL HYDRATE	05/07/91	Screen	20/08/91(*)	Day 42
	114	Female	Placebo	YES	CHLORAL HYDRATE	26/08/91	Screen	11/10/91(*)	Day 42
					NIFLURIL	30/09/91	Day 35	04/10/91	Day 35
					CHLORAL HYDRATE	13/11/91	Screen	31/12/91(*)	Day 42

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11

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
4/4	175	Female	Imipramine	YES	CHLORAL HYDRATE	11/02/92	Day 7	25/03/92(*)	Day 42
	176	Female	Placebo	NO	SULFARLEN	14/02/92	Day 7	25/03/92(*)	Day 42
	178	Female	Reboxetine	YES	CHLORAL HYDRATE	11/03/92	Screen	10/04/92	Day 28
	179	Female	Placebo	NO	SULFARLEN	18/05/92	Day 21	08/06/92(*)	Day 42
		Female	Placebo	NO	CHLORAL HYDRATE	07/09/92	Screen	29/09/92	Day 21
9	180	Male	Reboxetine	YES	TRENORIDIOL	07/09/92	Screen	29/09/92(*)	Day 21
6		Male	Reboxetine	YES	CHLORAL HYDRATE	30/09/92	Screen	17/11/92(*)	Day 42
9		Male	Reboxetine	YES	HEPT-A-NYL	03/11/92	Day 28	17/11/92(*)	Day 42
5/1	127	Male	Reboxetine	YES	CHLORAL HYDRATE	28/05/91	Screen	26/06/91	Day 21
	128	Female	Reboxetine	YES	CHLORAL HYDRATE	09/06/91	Screen	13/06/91	Day 7
	130	Male	Placebo	YES	AMOXICILLIN	12/03/92	Day 14	20/03/92	Day 21
		Male	Placebo	YES	ASPIRINE	12/03/92	Day 14	20/03/92	Day 21
		Male	Placebo	YES	DOXYCYCLINE	25/03/92	Day 21	07/04/92	Day 35
	132	Male	Imipramine	YES	CHLORAL HYDRATE	23/06/92	Screen	30/07/92	Day 42
		Male	Placebo	NO	METRONIDAZOLE	08/07/92	Day 14	06/08/92(*)	Day 42
		Male	Placebo	NO	TIAPRIDAL	18/06/92	Screen	22/06/92	Screen

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

12

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
5/2	121	Female	Imipramine	NO	CHLORAL HYDRATE	26/12/91	Day 7	27/12/91	Day 7
	125	Male	Reboxetine	YES	METOCLOPRAMIDE	18/02/91	Day 21	20/02/91	Day 21
5/3	133	Male	Placebo	NO	CHLORAL HYDRATE	04/12/91	Day 7	12/12/91(*)	Day 14
6/1	151	Male	Imipramine	NO	CHLORAL HYDRATE	13/01/92	Screen	15/01/92	Screen
	152	Female	Reboxetine	YES	ACETYLSALICYLIC ACID	04/03/92	Day 14	08/03/92	Day 14
					AMOXICILLIN + CLAVULANIC ACID	04/03/92	Day 14	08/03/92	Day 14
					CHLORAL HYDRATE	17/02/92	Screen	07/04/92(*)	Day 42
					ERCEPURYL	29/03/92	Day 35	03/04/92	Day 42
					INDIUM	29/03/92	Day 35	03/04/92	Day 42
					MOTILIUM	29/03/92	Day 35	03/04/92	Day 42
					PRIMPERAN	29/03/92	Day 35	03/04/92	Day 42
153		Male	Reboxetine	YES	CHLORAL HYDRATE	18/02/91	Screen	18/03/91	Screen
154		Female	Imipramine	NO	NOCTEC	25/03/92	Screen	06/04/92(*)	Screen
155		Male	Placebo	NO	CHLORAL HYDRATE	01/07/92	Screen	04/08/92(*)	Day 28
					LIPANOR	25/03/92	Screen	04/08/92(*)	Day 28
156		Female	Placebo	YES	CAPTEA	10/91	Screen	19/10/92(*)	Day 42

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13

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 8.0
 CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
6/2	159	Male	Imipramine	YES	CHLORAL HYDRATE	13/07/91	Day 7	24/08/91(*)	Day 42
	160	Male	Placebo	YES	CHLORAL HYDRATE	23/11/91	Day 7	04/01/92(*)	Day 42
	161	Female	Reboxetine	NO	RUFOL	06/03/92	Day 21	18/03/92(*)	Day 28
	169	Female	Imipramine	NO	RENITEC	09/12/91(\$)	Screen	15/01/92(*)	Day 21
	171	Female	Imipramine	YES	MAALOX	04/08/92	Day 14	11/08/92	Day 21
6/3	166	Female	Reboxetine	NO	HEPT-A-MYL	01/06/91	Screen	29/10/91(*)	Day 7
	168	Female	Placebo	NO	CHLORAL HYDRATE	21/11/91	Screen	02/12/91	Day 7
7/02	182	Male	Placebo	YES	SOSTREIL	08/91	Screen	03/01/92(*)	Day 42
	183	Male	Imipramine	NO	IODINE	88	Screen	18/01/92(*)	Day 21
					TAFIL	30/12/91(\$)	Screen	30/12/91	Screen
					TENDORIN	91	Screen	18/01/92(*)	Day 21
	185	Male	Reboxetine	NO	DORYL	12/04/92	Day 7	05/05/92(*)	Day 28
					EUGLUCON N	88	Screen	05/05/92(*)	Day 28
8/A	235	Female	Placebo	YES	CALCITONIN	20/09/92	Screen	24/11/92(*)	Day 42
	238	Female	Reboxetine	YES	CALCITONIN	90	Screen	24/11/92(*)	Day 42
	239	Female	Imipramine	YES	DILZENE	88	Screen	26/11/92(*)	Day 42

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9
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14

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
8/A	239	Female	Imipramine	YES	ISMO	88	Screen	26/11/92(*)	Day 42
	554	Male	Reboxetine	YES	AMLODIPINE	89	Screen	26/11/92(*)	Day 42
	555	Female	Reboxetine	YES	NORAYID	91	Screen	26/11/92(*)	Day 42
					SUGIAN	90	Screen	26/11/92(*)	Day 42
					QUINAPRIL	89	Screen	26/11/92(*)	Day 42
9	241	Female	Placebo	NO	CHLORAL HYDRATE	24/01/91	Screen	18/02/91	Day 14
	242	Female	Reboxetine	NO	CHLORAL HYDRATE	13/02/91	Screen	11/03/91	Day 21
9	243	Female	Reboxetine	NO	SIMETHICONE	04/03/91	Day 14	11/03/91(*)	Day 21
22	244	Female	Imipramine	NO	CHLORAL HYDRATE	16/02/91	Screen	06/03/91(*)	Day 14
	245	Female	Imipramine	YES	CHLORAL HYDRATE	14/02/91	Day 7	13/03/91	Day 28
	246	Female	Placebo	NO	RAMITIDINE	27/02/91	Day 14	13/03/91(*)	Day 28
	247	Female	Placebo	NO	CHLORAL HYDRATE	18/02/91	Screen	04/04/91	Day 42
	248	Male	Placebo	NO	CHLORAL HYDRATE	18/02/91	Screen	17/03/91	Day 28
	249	Female	Reboxetine	NO	CHLORAL HYDRATE	21/02/91	Screen	26/03/91(*)	Day 28
					CHLORAL HYDRATE	04/03/91	Screen	21/03/91	Day 14
					CHLORAL HYDRATE	04/03/91	Screen	11/03/91(*)	Day 7

(*) - start date missing = screening date
(*) - end date missing = last dose taken date

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15

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0

CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
9	250	Female	Imipramine	NO	CHLORAL HYDRATE	07/03/91	Day 7	07/04/91	Day 28
					ENALAPRIL MALEATE	89	Screen	08/04/91(*)	Day 28
					LAEYOLAC	11/03/91	Day 7	08/04/91(*)	Day 28
					MAALOX	02/04/91	Day 28	08/04/91(*)	Day 28
	252	Female	Reboxetine	NO	CHLORAL HYDRATE	28/03/91	Screen	20/04/91	Day 21
					TRASITENSIN	90	Screen	20/04/91(*)	Day 21
	253	Female	Reboxetine	NO	CHLORAL HYDRATE	29/03/91	Screen	08/04/91	Day 7
	254	Female	Imipramine	NO	CHLORAL HYDRATE	05/04/91	Screen	17/04/91	Day 14
	255	Female	Reboxetine	NO	CHLORAL HYDRATE	08/05/91	Screen	06/06/91	Day 28
	256	Female	Imipramine	YES	CHLORAL HYDRATE	23/05/91	Day 7	08/07/91	Day 42
					EFFORTIL	01/07/91	Day 35	08/07/91(*)	Day 42
					LAEYOLAC	01/07/91	Day 35	08/07/91(*)	Day 42
					MAALOX	01/07/91	Day 35	08/07/91(*)	Day 42
	257	Male	Placebo	NO	CHLORAL HYDRATE	21/06/91	Screen	01/07/91	Day 7
	258	Male	Placebo	NO	CHLORAL HYDRATE	25/06/91	Screen	10/07/91	Day 14
11	319	Male	Placebo	YES	CHLORAL HYDRATE	23/08/91	Day 28	24/08/91	Day 28
						30/08/91	Day 35	12/09/91	Day 42

(*) - start date missing = screening date
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16

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
11	320	Male	Imipramine	YES	CHLORAL HYDRATE	22/08/91	Day 14	26/09/91(*)	Day 42
	322	Female	Reboxetine	YES	CHLORAL HYDRATE	01/11/91	Day 42	04/11/91	Day 42
	324	Male	Imipramine	YES	CHLORAL HYDRATE	03/01/92	Day 35	15/01/92	Day 42
	326	Male	Placebo	YES	DIAZEPAM	25/01/92	Day 14	29/01/92	Day 14
	329	Female	Placebo	YES	CAPTOPRIL	91	Screen	21/05/92(*)	Day 42
	336	Female	Imipramine	NO	BRUFEN	15/06/92(\$)	Screen	25/06/92(*)	Day 7
					PREMARIN	15/06/92(\$)	Screen	25/06/92(*)	Day 7
	337	Female	Reboxetine	YES	CHLORAL HYDRATE	30/07/92	Day 35	13/08/92(*)	Day 42
12	367	Female	Reboxetine	YES	CHLORAL HYDRATE	15/12/91 24/01/92	Screen Day 42	22/01/92 31/01/92	Day 35 Day 42
	368	Female	Placebo	YES	HYDROCHLOROTHIAZIDE WITH ACETAMINOPHEN	15/12/91 05/01/92	Screen Day 14	06/01/92 05/01/92	Day 21 Day 14
	369	Female	Imipramine	NO	CHLORAL HYDRATE	18/04/92 11/05/92	Screen Day 21	22/04/92 11/05/92	Screen Day 21
					CLONAZEPAM	17/04/92	Screen	21/04/92	Screen

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17

PIARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
12	369	Female	Imipramine	NO	NEDROXYPROGESTERONE ACETA	14/04/92	Screen	13/05/92(*)	Day 21
					OESTROGEN-HOLZINGER	14/04/92	Screen	13/05/92(*)	Day 21
	370	Male	Placebo	NO	CHLORAL HYDRATE	22/04/92	Screen	19/05/92	Day 21
					LORAZEPAM	15/05/92	Day 21	15/05/92	Day 21
					NIFEDIPINE	13/04/92	Screen	20/05/92(*)	Day 28
					NITRAZEPAM	22/04/92	Screen	24/04/92	Screen
					PIMOZINE	23/04/92	Screen	27/04/92	Screen
					PROCYCLIDINE HYDROCHLORID	23/04/92	Screen	27/04/92	Screen
					ACETAMINOPHEN	17/04/92	Screen	28/04/92	Screen
	371	Female	Imipramine	NO	BACITRACIN	16/04/92	Screen	22/04/92	Screen
					CHLORAL HYDRATE	24/04/92	Screen	07/05/92	Day 7
					PSEUDOEPHEDRINE HYDROCHLORO	22/04/92	Screen	27/04/92	Screen
					TEMAZEPAM	15/04/92	Screen	21/04/92	Screen
	372	Male	Reboxetine	YES	ACEBUTOLOL HYDROCHLORIDE	11/06/92	Day 14	13/07/92(*)	Day 42
					ACETAMINOPHEN	02/06/92	Day 7	04/06/92	Day 7
					CHLORAL HYDRATE	02/06/92	Day 7	13/07/92	Day 42

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18

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Completa as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
12	372	Male	Reboxetine	YES	DIHENHYDRINATE	03/06/92	Day 7	03/06/92	Day 7
	374	Female	Placebo	NO	NIFEDIPINE	03/06/92	Day 7	03/06/92	Day 7
	375	Male	Imipramine	NO	CHLORAL HYDRATE	08/06/92	Screen	09/06/92	Day 7
					ACETAMINOPHEN	13/06/92	Screen	13/06/92	Screen
						15/06/92	Screen	15/06/92	Screen
					CHLORAL HYDRATE	11/06/92	Screen	18/06/92	Day 7
					CLONAZEPAM	18/06/92	Day 7	18/06/92	Day 7
					FLURAZEPAM	18/06/92	Day 7	18/06/92	Day 7
13	13	Male	Placebo	YES	TEMAZEPAM	03/04/91	Screen	24/05/91(*)	Day 42
	15	Female	Imipramine	YES	CANESTEN	01/07/91	Day 14	15/08/91(*)	Day 42
					ERYTHRONICIN	30/06/91	Day 7	10/07/91	Day 7
					PANADOL	01/07/91	Day 7	15/08/91(*)	Day 42
					VENTOLIN	01/07/91	Day 7	15/08/91(*)	Day 42
16		Male	Imipramine	NO	HYDROXYUREA	18/11/91	Screen	24/11/91	Screen
						30/11/91	Screen	16/01/92(*)	Day 42
18		Male	Reboxetine	YES	PANADOL	22/07/92	Day 35	26/07/92	Day 35
410		Male	Placebo	YES	PANADOL	14/02/92	Day 7	20/02/92	Day 7

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19

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
13	411	Female	Imipramine	YES	AGAROL	91	Screen	04/04/92	Day 7
					ASPIRINE	25/03/92	Screen	08/05/92(*)	Day 42
					DIAZEPAM	18/03/92	Screen	23/03/92	Screen
					NU-LAX	18/03/92	Day 14	08/05/92(*)	Day 42
					PANADOL	18/04/92	Day 28	08/05/92(*)	Day 42
					SUDAFED	02/04/92 22/04/92	Day 7 Day 28	04/04/92 29/04/92	Day 7 Day 35
					TEHAZEPAM	18/03/92	Day 14	29/03/92	Day 14
14	19	Female	Reboxetine	NO	TRIMETHOPRIM	06/04/92	Day 7	15/04/92	Day 7
					FLUCLOXACILLIN	30/04/92	Day 7	02/05/92	Day 7
					PENICILLIN G	30/04/92	Day 7	02/05/92	Day 7
					TETANUS IMMUNOGLOBULIN	30/04/92	Day 7	30/04/92	Day 7
					TETANUS TOXOID	30/04/92	Day 7	30/04/92	Day 7
					CHLORAL HYDRATE	15/07/92	Screen	19/07/92	Screen
15	25	Female	Reboxetine	YES	PARACETAMOL	20/06/91 20/07/91	Day 7 Day 35	23/06/91 22/07/91	Day 7 Day 35
					TEHAZEPAM	02/04/91	Screen	29/07/91(*)	Day 42

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20

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
15	27	Female	Imipramine	YES	NORETHISTERONE	06/85	Screen	13/08/91(*)	Day 42
					OESTRADIOL	06/85	Screen	13/08/91(*)	Day 42
	28	Female	Reboxetine	YES	AUGHENTIN	03/09/91	Day 28	07/09/91	Day 35
					SENOKOT	31/08/91	Day 28	02/09/91	Day 28
						06/09/91	Day 35	10/09/91	Day 35
						15/09/91	Day 42	18/09/91	Day 42
					TEMAZEPAM	21/05/91	Screen	11/09/91	Day 35
	29	Male	Placebo	NO	TEMAZEPAM	22/08/91	Screen	08/09/91	Day 14
						17/09/91	Day 21	18/09/91	Day 21
	403	Female	Imipramine	YES	TEMAZEPAM	02/10/91	Day 7	14/11/91(*)	Day 42
	405	Female	Placebo	YES	MULTIVITAMINS	06/91	Screen	23/12/91(*)	Day 42
	407	Female	Reboxetine	YES	PARACETAMOL	21/12/91	Day 21	22/12/91	Day 21
						10/01/92	Day 42	13/01/92	Day 42
	408	Female	Placebo	YES	PARACETAMOL	03/02/92	Day 14	04/02/92	Day 21
					TEMAZEPAM	11/02/92	Day 35	04/03/92(*)	Day 42
	418	Female	Placebo	YES	CALCIUM GLUCONATE	71	Screen	12/03/92(*)	Day 42
					CALCIUM LACTATE	71	Screen	12/03/92(*)	Day 42
					SENOKOT	06/03/92	Day 42	12/03/92(*)	Day 42

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978

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21

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
15	418	Female	Placebo	YES	TEMAZEPAM	16/10/89	Screen	12/03/92(*)	Day 42
	419	Female	Placebo	YES	AMOXICILLIN	06/06/92	Day 42	09/06/92(*)	Day 42
					ASPIRINE	01/06/92	Day 35	03/06/92	Day 42
					PARACETANOL	11/05/92 22/05/92	Day 14 Day 28	11/05/92 24/05/92	Day 14 Day 28
					URAL	06/06/92	Day 42	09/06/92(*)	Day 42

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(§) - start date missing = screening date
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1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	z Compl. day	z Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overtdose (xx)
1	1	Imipramine	10/04/91	10/04/91	1	100	50	100.0	100.0	9m	50	50	
			11/04/91	12/04/91	2	100	100	100.0	100.0		50	50	
			13/04/91	28/04/91	16	150	150	100.0	100.0		50	100	
			29/04/91	29/04/91	1	150	50	33.3	96.7	1e	50	50	
			30/04/91	09/05/91	10	150	150	100.0	97.8		50	100	
			10/05/91	10/05/91	1	150	0.0	0.0	94.6	10m 10e	50	100	
			11/05/91	11/05/91	1	150	150	100.0	94.8		50	100	
			12/05/91	13/05/91	2	150	50	33.3	91.2	10e	50	50	
			14/05/91	21/05/91	8	150	150	100.0	92.9		50	100	
			22/05/91	22/05/91	1	150	50	100.0	93.0	9e	50	50	
					43								
2	2	Reboxetine	15/04/91	15/04/91	1	8	4	100.0	100.0	9m	4	4	
			16/04/91	12/05/91	27	8	8	100.0	100.0		4	4	
			13/05/91	26/05/91	14	10	10	100.0	100.0		4	6	
			27/05/91	27/05/91	1	10	4	100.0	100.0	9e	4	4	
								43					
3	3	Imipramine	06/05/91	06/05/91	1	100	50	100.0	100.0	9m	50	50	
			07/05/91	08/05/91	2	100	100	100.0	100.0		50	50	
			09/05/91	02/06/91	25	150	150	100.0	100.0		50	100	
			03/06/91	03/06/91	1	200	150	100.0	100.0		50	100	
			04/06/91	16/06/91	13	200	200	100.0	100.0		100	100	
								42					
4	4	Placebo	04/06/91	04/06/91	1	0	0	100.0	100.0	9m	0	0	
			05/06/91	15/07/91	41	0	0	100.0	100.0		0	0	
			16/07/91	16/07/91	1	0	0	100.0	100.0	9e	0	0	
					43								
5	5	Reboxetine	12/06/91	12/06/91	1	8	4	100.0	100.0	9m	4	4	
			13/06/91	01/07/91	19	8	8	100.0	100.0		4	4	
			02/07/91	02/07/91	1	8	4	100.0	100.0	6e	4	4	
					21								
6	6	Placebo	23/05/91	23/05/91	1	0	0	100.0	100.0	9m	0	0	
			24/05/91	05/07/91	43	0	0	100.0	100.0		0	0	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(xx) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 8=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

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2

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Z Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)			
1	7	Reboxetine	27/08/91	27/08/91	1	8	4	100.0	100.0	9m	4	4				
			28/08/91	05/09/91	9	8	8	100.0	100.0		4	4				
			06/09/91	06/09/91	1	8	4	50.0	95.5	1e	4	4				
			07/09/91	07/10/91	31	8	8	100.0	98.8	9e	4	4				
			08/10/91	08/10/91	1	8	4	100.0	98.8		4					
8	Placebo	Placebo	05/09/91	18/09/91	14	0	0	100.0	100.0		0	0				
			19/09/91	20/09/91	2	0	0	100.0	100.0	10e	0	0				
			21/09/91	24/09/91	4	0	0	100.0	100.0		0	0				
			25/09/91	25/09/91	1	0	0	100.0	100.0	1m	0	0				
			26/09/91	27/09/91	2	0	0	100.0	100.0	4e	0	0				
			28/09/91	18/10/91	21	0	0	100.0	100.0		0	0				
			19/10/91	19/10/91	1	0	0	100.0	100.0	9e	0	0				
9	Reboxetine	Reboxetine	27/11/91	27/11/91	1	8	4	100.0	100.0	9m	4	4				
			28/11/91	17/12/91	20	8	8	100.0	100.0		4	4				
			18/12/91	05/01/92	19	10	10	100.0	100.0		4	4				
			06/01/92	06/01/92	1	10	4	100.0	100.0	9e	4	4				
10	Placebo	Placebo	24/09/91	24/09/91	1	0	0	100.0	100.0	9m	0	0				
			25/09/91	13/10/91	19	0	0	100.0	100.0		0	0				
			14/10/91	14/10/91	1	0	0	100.0	100.0	10e	0	0				
			15/10/91	03/11/91	20	0	0	100.0	100.0		0	0				
			04/11/91	04/11/91	1	0	0	100.0	100.0	9e	0	0				
11	Imipramine	Imipramine	10/10/91	12/10/91	3	100	100	100.0	100.0		50	50				
			13/10/91	13/10/91	1	150	150	100.0	100.0		50	100				
12	Imipramine	Imipramine	18/10/91	20/10/91	3	100	100	100.0	100.0		50	50				
			21/10/91	29/11/91	40	150	150	100.0	100.0		50	100				

44

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(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 9=low daily dose in one administration
m = morning, e = evening

81

9550082

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3

PHARMACIA CNS 88D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
1	12	Imipramine	30/11/91	30/11/91	1	150	50	100.0	100.0	9e	50		
					44								
412		Reboxetine	13/11/91	13/11/91	1	8	4	100.0	100.0	9m		4	
			14/11/91	03/12/91	20	8	8	100.0	100.0		4	4	
			04/12/91	22/12/91	19	10	10	100.0	100.0		4	6	
			23/12/91	23/12/91	1	10	4	100.0	100.0	6e	4		
					41								
413		Placebo	09/12/91	19/01/92	42	0	0	100.0	100.0		0	0	
			20/01/92	20/01/92	1	0	0	100.0	100.0	9a	0		
					43								
414		Imipramine	22/01/92	24/01/92	3	100	100	100.0	100.0		50	50	
			25/01/92	29/01/92	5	150	150	100.0	100.0		50	100	
					8								
415		Imipramine	14/01/92	14/01/92	1	100	50	100.0	100.0	9m		50	
			15/01/92	16/01/92	2	100	100	100.0	100.0		50	50	
			17/01/92	27/01/92	11	150	150	100.0	100.0		50	100	
			28/01/92	28/01/92	1	150	50	33.3	95.6	10e	50		
			29/01/92	05/02/92	8	150	150	100.0	97.1		50	100	
			06/02/92	06/02/92	1	150	0	0.0	93.1	10m 10e	50		
			07/02/92	27/02/92	21	150	150	100.0	96.3		50	100	
					45								
416		Reboxetine	17/01/92	17/01/92	1	8	4	100.0	100.0	9m		4	
			18/01/92	23/01/92	6	8	8	100.0	100.0		4	4	
			24/01/92	24/01/92	1	8	12	100.0	100.0	9a	8	4	yes
			25/01/92	28/01/92	4	8	8	100.0	100.0		4	4	
					12								
421		Imipramine	27/02/92	27/02/92	1	100	50	100.0	100.0	9m		50	
			28/02/92	29/02/92	2	100	100	100.0	100.0		50	50	
			01/03/92	09/04/92	40	150	150	100.0	100.0		50	100	

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	X Compl. day	Z Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
1	422	Imipramine	05/08/92	07/08/92	43	100	100	100.0	100.0		50	50	
			08/08/92	14/08/92	7	150	150	100.0	100.0		50	100	
			15/08/92	15/08/92	1	150	50	33.3	93.9	1e	50	50	
			16/08/92	19/08/92	4	150	150	100.0	95.6		50	100	
			20/08/92	20/08/92	1	150	50	33.3	91.7	1e	50	50	
			21/08/92	25/08/92	5	150	150	100.0	93.7		50	100	
			26/08/92	26/08/92	1	150	50	33.3	90.9	1e	50	50	
			27/08/92	27/08/92	1	150	100	66.7	89.9	1m	50	100	
			28/08/92	01/09/92	5	150	150	100.0	91.7		50	100	
			02/09/92	02/09/92	1	150	0.0	0.0	88.5	10m 10e	50	100	
			03/09/92	09/09/92	7	150	150	100.0	90.7		50	100	
9	00	C3	10/09/92	10/09/92	1	150	0.0	0.0	88.3	1m 1e	50	100	
			11/09/92	17/09/92	7	150	150	100.0	90.2		50	100	
					44								
2/1	49	Placebo	18/05/91	28/06/91	42	0	0	100.0	100.0		0	0	
					42								
50	Reboxetine	27/12/91	05/02/92	41	8	8	100.0	100.0		4	4		
		06/02/92	06/02/92	1	8	4	100.0	100.0	6e	4	4		
51	Imipramine	02/02/92	04/02/92	3	100	100	100.0	100.0		50	50		
		05/02/92	15/03/92	40	150	150	100.0	100.0		50	100		
2/2	43	Imipramine	18/04/91	18/04/91	1	100	50	100.0	100.0		50	50	
			19/04/91	20/04/91	2	100	100	100.0	100.0	9m	50	100	
			21/04/91	23/04/91	3	150	150	100.0	100.0		50	100	
			24/04/91	24/04/91	1	150	50	100.0	100.0	3e	50	50	
			25/04/91	02/05/91	8	150	100.0	100.0	100.0	3m 3e	50	100	
			03/05/91	16/05/91	14	150	150	100.0	100.0		50	100	
44	Imipramine	19/07/91	19/07/91	1	100	0.0	0.0	0.0	9m 1e				

(*) 4=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 m = morning, e = evening

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5

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Z Compl. day	Z Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
2/2	44	Imipramine	20/07/91	21/07/91	2	100	100	100.0	66.7		50	50	
			22/07/91	29/08/91	39	150	150	100.0	97.6		50	100	
					42								
45	Reboxetine	08/09/91	29/09/91	22	8	8	100.0	100.0			4	4	
		30/09/91	20/10/91	21	10	10	100.0	100.0			4	6	
					43								
46	Placebo	26/09/91	26/09/91	1	0	0	100.0	100.0		9m	0	0	
		27/09/91	10/10/91	14	0	0	100.0	100.0			0	0	
		11/10/91	16/10/91	6	0	0	100.0	100.0		3m 3oa	0	0	
		17/10/91	17/10/91	1	0	0	100.0	100.0		3m	0	0	
		18/10/91	22/10/91	5	0	0	100.0	100.0			0	0	
		23/10/91	23/10/91	1	0	0	100.0	100.0		9e	0	0	
					28								
47	Placebo	24/03/92	05/04/92	13	0	0	100.0	100.0			0	0	
		06/04/92	06/04/92	1	0	0	100.0	100.0		1e	0	0	
		07/04/92	02/05/92	26	0	0	100.0	100.0			0	0	
		03/05/92	03/05/92	1	0	0	100.0	100.0		1m	0	0	
					42								
48	Reboxetine	07/04/92	04/05/92	28	8	8	100.0	100.0			4	4	
		05/05/92	05/05/92	1	8	8	0.0	96.6	1m 1e				
		06/05/92	19/05/92	14	8	8	100.0	97.7			4	4	
					43								
2/3	36/A	Imipramine	07/03/91	09/03/91	3	100	100	100.0	100.0		50	50	
			10/03/91	17/04/91	39	150	150	100.0	100.0		50	100	
					42								
37	Reboxetine	27/03/91	07/05/91	42	8	8	100.0	100.0			4	4	
					42								
38	Placebo	14/08/91	25/09/91	43	0	0	100.0	100.0			0	0	

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

6

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Z Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)	
2/3	39	Imipramine	10/08/91	12/08/91	3	100	100	100.0	100.0		50	50		
			13/08/91	20/09/91	39	150	150	100.0	100.0		50	100		
			43											
40	Reboxetine	24/10/91	04/12/91	42	8	8	100.0	100.0	100.0		4	4		
		42												
41	Placebo	03/10/91	13/11/91	42	0	0	100.0	100.0	100.0		0	0		
		42												
42	Imipramine	19/05/92	21/05/92	3	100	100	100.0	100.0	100.0		50	50		
		22/05/92	30/06/92	40	150	150	100.0	100.0	100.0		50	100		
43														
2/4	31	Placebo	26/03/91	05/05/91	41	0	0	100.0	100.0	100.0		0	0	
			41											
32	Reboxetine	26/10/91	06/12/91	42	8	8	100.0	100.0	100.0		4	4		
		42												
33	Imipramine	29/05/91	29/05/91	1	100	50	100.0	100.0	100.0			50		
		30/05/91	31/05/91	2	100	100	100.0	100.0	100.0	9m	50	50		
		01/06/91	09/07/91	39	150	150	100.0	100.0	100.0		50	100		
		10/07/91	10/07/91	1	150	50	100.0	100.0	100.0	9e	50	50		
43														
34	Placebo	17/04/92	28/05/92	42	0	0	100.0	100.0	100.0		0	0		
		42												
35	Reboxetine	15/09/92	26/10/92	42	8	8	100.0	100.0	100.0		4	4		
		42												

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
2/4	36	Imipramine	12/02/92	14/02/92	3	100	100	100.0	100.0		50	50	
			15/02/92	24/03/92	39	150	100.0	100.0		50	100		
2/5	73	Placebo	07/02/92	20/03/92	43	0	0	100.0	100.0		0	0	
					43								
74		Reboxetine	21/06/92	01/08/92	42	8	8	100.0	100.0		4	4	
					42								
75		Imipramine	11/09/92	13/09/92	3	100	100	100.0	100.0		50	50	
			14/09/92	22/10/92	39	150	100.0	100.0		50	100		
76		Imipramine	15/09/92	17/09/92	3	100	100	100.0	100.0		50	50	
			18/09/92	26/10/92	39	150	100.0	100.0		50	100		
77		Placebo	22/09/92	02/11/92	42	0	0	100.0	100.0		0	0	
					42								
78		Reboxetine	10/10/92	13/11/92	35	8	8	100.0	100.0		4	4	
					35								
2/6	55	Reboxetine	12/06/92	02/07/92	21	8	8	100.0	100.0		4	4	
			03/07/92	23/07/92	21	8	18	100.0	100.0		8	10	(3 - m) (3 - e)
56		Reboxetine	12/06/92	02/07/92	21	8	8	100.0	100.0		4	4	
			03/07/92	23/07/92	21	8	18	100.0	100.0		8	10	(3 - m) (3 - e)

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(xx) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration, m = morning, e = evening

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

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EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
2/6	57	Imipramine	05/05/92	07/05/92	42	100	100	100.0	100.0		50	50	
			08/05/92	25/05/92	18	150	150	100.0	100.0		50	100	
			26/05/92	15/06/92	21	150	350	100.0	100.0		150	200	(3 - m) (3 - e)
58	Placebo	18/05/92	08/06/92	22	0	0	100.0	100.0	100.0		0	0	
		09/06/92	29/06/92	21	0	0	100.0	100.0	100.0		0	0	(3 - m) (3 - e)
				43									
59	Placebo	27/05/92	16/06/92	21	0	0	100.0	100.0	100.0		0	0	
		17/06/92	23/06/92	7	0	0	100.0	100.0	100.0		0	0	(3 - m) (3 - e)
				28									
60	Imipramine	12/05/92	14/05/92	3	100	100	100.0	100.0	100.0		50	50	
		15/05/92	01/06/92	18	150	150	100.0	100.0	100.0		50	100	
		02/06/92	22/06/92	21	150	350	100.0	100.0	100.0		150	200	(3 - m) (3 - e)
3/4	Imipramine	05/03/91	07/03/91	42	100	100	100.0	100.0	100.0		50	50	
		08/03/91	20/03/91	13	150	150	100.0	100.0	100.0		50	100	
		21/03/91	21/03/91	1	150	100	66.7	98.0	1m	100	100		
61	Placebo	22/03/91	22/03/91	1	150	150	100.0	98.1		50	50		
		23/03/91	23/03/91	1	150	50	33.3	94.7	1e	50	100		
		24/03/91	31/03/91	8	150	150	100.0	96.3		50	100		
62	Imipramine	01/04/91	01/04/91	1	150	50	33.3	94.0	1e	50	50		
		02/04/91	07/04/91	6	150	150	100.0	95.1		50	100		
		08/04/91	08/04/91	1	150	50	33.3	93.3	1e	50	100		
63	Placebo	16/04/91	18/04/91	35	100	100	100.0	100.0	100.0		50	50	
		19/04/91	26/05/91	38	150	150	100.0	100.0	100.0		50	100	
		13/05/91	23/06/91	42	0	0	100.0	100.0	100.0		0	0	

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(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
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9550082

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9

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Z Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
3/1	64	Placebo	14/03/91	01/04/91	19	0	0	100.0	100.0		0	0	
			02/04/91	02/04/91	1	0	0	100.0	100.0	1e	0	0	
			03/04/91	24/04/91	22	0	0	100.0	100.0		0	0	
				42									
65	Reboxetine	16/09/91	27/10/91	42	8	8	100.0	100.0			4	4	
				42									
66	Reboxetine	10/06/91	21/07/91	42	8	8	100.0	100.0			4	4	
				42									
139	Imipramine	03/09/91	05/09/91	3	100	100	100.0	100.0			50	50	
		06/09/91	12/09/91	7	150	150	100.0	100.0			50	100	
				10									
140	Placebo	12/09/91	23/10/91	42	0	0	100.0	100.0			0	0	
				42									
141	Placebo	03/10/91	14/11/91	43	0	0	100.0	100.0			0	0	
				43									
142	Imipramine	18/11/91	20/11/91	3	100	100	100.0	100.0			50	50	
		21/11/91	08/12/91	18	150	150	100.0	100.0			50	100	
				21									
143	Reboxetine	15/04/92	15/04/92	1	8	4	100.0	100.0			4	4	
		16/04/92	19/05/92	34	8	8	100.0	100.0			4	4	
		20/05/92	20/05/92	1	8	4	100.0	100.0	6e		4	4	
				36									
144	Reboxetine	09/06/92	09/06/92	1	8	4	100.0	100.0			4	4	
		10/06/92	22/07/92	43	8	8	100.0	100.0			4	4	

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 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
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9550082

10

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
3/1	451	Reboxetine	20/01/92	20/01/92	1	8	4	100.0	100.0	9m	4	4	
			21/01/92	31/01/92	11	8	8	100.0	100.0		4	4	
			01/02/92	01/02/92	1	8	4	100.0	100.0	6e	4		
					13								
452	Placebo	22/01/92	22/01/92	1	0	0	100.0	100.0	9m	0	0		
		23/01/92	03/03/92	41	0	0	100.0	100.0		0	0		
		04/03/92	04/03/92	1	0	0	100.0	100.0	9e	0			
					43								
453	Imipramine	29/01/92	29/01/92	1	100	50	100.0	100.0	9m	50	50		
		30/01/92	31/01/92	2	100	100	100.0	100.0		50	50		
		01/02/92	10/03/92	39	150	150	100.0	100.0		50	100		
					42								
454	Reboxetine	17/02/92	17/02/92	1	8	4	100.0	100.0	9m	4	4		
		18/02/92	31/03/92	43	8	8	100.0	100.0		4	4		
		01/04/92	01/04/92	1	8	4	100.0	100.0	9e	4			
					45								
455	Placebo	11/03/92	11/03/92	1	0	0	100.0	100.0	9m	0	0		
		12/03/92	22/04/92	42	0	0	100.0	100.0		0	0		
					43								
456	Imipramine	25/03/92	25/03/92	1	100	50	100.0	100.0	9m	50	50		
		26/03/92	27/03/92	2	100	100	100.0	100.0		50	50		
		28/03/92	02/04/92	6	150	150	100.0	100.0		50	100		
					1	150	50	100.0	100.0	3e	50		
					10								
3/2	455/A	Reboxetine	29/01/91	25/02/91	28	8	8	100.0	100.0		4	4	
			26/02/91	27/02/91	2	8	18	100.0	100.0		8	10	(3 - m) (3 - e)
			28/02/91	04/03/91	5	8	10	100.0	100.0		4	6	
			05/03/91	11/03/91	7	10	10	100.0	100.0		4	6	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(xx) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

11

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
3/3	67	Placebo	18/07/91	28/08/91	42	0	0	100.0	100.0		0	0	0
					42								
					42								
68	Reboxetine	21/01/92	02/03/92	42	8	8	100.0	100.0	100.0	4	4	4	
				42									
				42									
69	Placebo	04/02/92	16/03/92	42	0	0	100.0	100.0	100.0	0	0	0	
				42									
				42									
70	Imipramine	15/04/92	17/04/92	3	100	100	100.0	100.0	100.0		50	50	
				39									
				42									
71	Imipramine	16/04/92	18/04/92	3	100	100	100.0	100.0	100.0		50	50	
				39									
				42									
72	Reboxetine	25/07/92	04/09/92	42	8	8	100.0	100.0	100.0	4	4	4	
				42									
				42									
3/4	79	Imipramine	04/05/91	05/05/91	2	100	100	100.0	100.0		50	50	
					1								
					1								
					1								
					27								
					1								
11													
80	Imipramine	01/09/91	03/09/91	3	100	100	100.0	100.0	100.0		50	50	
				21									
				24									

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
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9550082

12

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PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Z Compl. day	Z Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
3/4	81	Reboxetine	17/05/91	27/06/91	42	8	8	100.0	100.0		4	4	
					42								
	82	Placebo	17/06/91	28/07/91	42	0	0	100.0	100.0		0	0	
					42								
	83	Placebo	17/06/91	17/06/91	1	0	0	100.0	100.0	9m	0	0	
					6	0	0	100.0	100.0		0	0	
			24/06/91	24/06/91	1	0	0	100.0	100.0	6e	0	0	
					8								
	84	Reboxetine	09/10/91	22/11/91	45	8	8	100.0	100.0		4	4	
					1	8	4	100.0	100.0	9e	4	4	
	85	Imipramine	29/10/91	31/10/91	3	100	100	100.0	100.0		50	50	
					38	150	150	100.0	100.0		50	100	
			01/11/91	08/12/91	41								
	86	Imipramine	03/12/91	05/12/91	3	100	100	100.0	100.0		50	50	
					40	150	150	100.0	100.0		50	100	
			15/01/92	15/01/92	1	150	50	100.0	100.0	9e	50	50	
					44								
	87	Placebo	09/12/91	19/01/92	42	0	0	100.0	100.0		0	0	
					42								
	88	Placebo	23/03/92	23/03/92	1	0	0	100.0	100.0		0	0	
					4	0	0	100.0	100.0	9m	0	0	
			28/03/92	28/03/92	1	0	0	100.0	100.0		0	0	
					1	0	0	100.0	100.0		0	0	
			30/03/92	30/03/92	1	0	0	100.0	100.0		0	0	
					20	0	0	100.0	100.0		0	0	
			20/04/92	21/04/92	2	0	0	100.0	100.0	4e	0	0	
					1	0	0	100.0	100.0	4m	0	0	
			23/04/92	07/05/92	15	0	0	100.0	100.0		0	0	
					42								

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (xx) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

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13

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PIARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (ng)	Daily dose (ng)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (ng)	Evening dose (ng)	Overdose (x)
3/4	88	Placebo	08/05/92	08/05/92	1	0	0	100.0	100.0	9e	0		
					47								
	89	Reboxetine	26/03/92	05/05/92	41	8	8	100.0	100.0		4	4	
			06/05/92	06/05/92	1	8	4	100.0	100.0	9e	4		
					42								
	90	Reboxetine	23/04/92	08/06/92	42	8	8	100.0	100.0		4	4	
					42								
	457	Placebo	22/05/92	11/06/92	21	0	0	100.0	100.0		0	0	
					21								
	458	Reboxetine	26/05/92	26/05/92	1	8	4	100.0	100.0	9m	4	4	
			27/05/92	08/06/92	13	8	8	100.0	100.0		4	4	
			09/06/92	09/06/92	1	8	4	100.0	100.0	6e	4		
					15								
	459	Placebo	02/06/92	18/06/92	17	0	0	100.0	100.0		0	0	
			19/06/92	20/06/92	2	0	0	100.0	100.0	10e	0		
			21/06/92	13/07/92	23	0	0	100.0	100.0		0	0	
					42								
	460	Reboxetine	19/08/92	20/08/92	2	8	8	100.0	100.0		4	4	
					2								
	461	Imipramine	17/09/92	17/09/92	1	100	50	100.0	100.0	9m	50	50	
			18/09/92	19/09/92	2	100	100	100.0	100.0		50	50	
			20/09/92	23/09/92	4	150	150	100.0	100.0		50	100	
			24/09/92	24/09/92	1	150	50	100.0	100.0	6e	50		
					8								
	462	Imipramine	29/09/92	29/09/92	1	100	50	100.0	100.0	9m	50	50	
			30/09/92	01/10/92	2	100	100	100.0	100.0		50	50	
			02/10/92	07/10/92	6	150	150	100.0	100.0		50	100	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

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14

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Z Compl. day	Reason (%)	Morning dose (mg)	Evening dose (mg)	Oversedose (**)
3/4	462	Imipramine	08/10/92	08/10/92	1	150	50	100.0	100.0	6e	50		
					10								
4/1	91	Imipramine	12/10/91	14/10/91	3	100	100	100.0	100.0		50	50	
			15/10/91	22/11/91	39	150	150	100.0	100.0		50	100	
					42								
92		Reboxetine	07/08/91	10/09/91	35	8	8	100.0	100.0		4	4	
			11/09/91	17/09/91	7	10	10	100.0	100.0		4	6	
					42								
93		Placebo	03/07/91	15/08/91	44	0	0	100.0	100.0		0	0	
			16/08/91	16/08/91	1	0	0	100.0	100.0	9a	0	0	
					45								
94		Placebo	05/07/91	19/07/91	15	0	0	100.0	100.0		0	0	
			20/07/91	23/07/91	4	0	0	100.0	100.0	4e	0	0	
			24/07/91	13/08/91	21	0	0	100.0	100.0		0	0	
					40								
95		Imipramine	03/06/91	05/06/91	3	100	100	100.0	100.0		50	50	
			06/06/91	16/07/91	41	150	150	100.0	100.0		50	100	
					44								
96		Reboxetine	04/09/91	16/10/91	43	8	8	100.0	100.0		4	4	
					43								
115		Reboxetine	06/05/92	16/06/92	42	8	8	100.0	100.0		4	4	
					42								
116		Imipramine	16/05/92	18/05/92	3	100	100	100.0	100.0		50	50	
			19/05/92	21/05/92	3	150	150	100.0	100.0		50	100	
			22/05/92	22/05/92	1	150	50	100.0	100.0	6e	50	50	

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(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

15

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Comp. day	X	Z	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
					7									
4/1	117	Imipramine	03/09/91	05/09/91	3	100	100	100.0	100.0	100.0		50	50	
			06/09/91	14/10/91	39	150	150	100.0	100.0			50	100	
					42									
	118	Reboxetine	23/05/92	03/07/92	42	8	8	100.0	100.0	100.0		4	4	
					42									
	120	Placebo	31/07/92	31/07/92	1	0	0	100.0	100.0	100.0	9m	0	0	
			01/08/92	11/09/92	42	0	0	100.0	100.0	100.0		0	0	
					43									
9	145	Imipramine	30/09/92	02/10/92	3	100	100	100.0	100.0	100.0		50	50	
9			03/10/92	05/10/92	3	150	150	100.0	100.0	100.0		50	100	
4			06/10/92	06/10/92	1	150	100	66.7	95.2	10m		100	100	
			07/10/92	10/11/92	35	150	150	100.0	99.2			50	100	
					42									
	146	Placebo	16/09/92	26/10/92	41	0	0	100.0	100.0	100.0		0	0	
			27/10/92	27/10/92	1	0	0	100.0	100.0	100.0	9a	0	0	
					42									
	147	Reboxetine	01/09/92	02/09/92	2	8	8	100.0	100.0	100.0		4	4	
			03/09/92	03/09/92	1	8	4	50.0	83.3	10e		4	4	
			04/09/92	12/10/92	39	8	8	100.0	98.8			4	4	
					42									
	148	Imipramine	26/09/92	28/09/92	3	100	100	100.0	100.0	100.0		50	50	
			29/09/92	06/11/92	39	150	150	100.0	100.0	100.0		50	100	
					42									
	149	Reboxetine	30/09/92	10/11/92	42	8	8	100.0	100.0	100.0		4	4	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(xx) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

16

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	X Compl. day	X Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
4/1	150	Placebo	30/09/92	10/11/92	42	0	0	100.0	100.0		0	0	0
					42	0	0	100.0	100.0		0	0	0
					42	0	0	100.0	100.0		0	0	0
4/2	93/A	Placebo	22/02/91	04/04/91	42	0	0	100.0	100.0		0	0	0
					42	0	0	100.0	100.0		0	0	0
					42	0	0	100.0	100.0		0	0	0
4/3	97	Placebo	27/03/91	07/05/91	42	0	0	100.0	100.0		0	0	0
					42	0	0	100.0	100.0		0	0	0
					42	0	0	100.0	100.0		0	0	0
4/3	98	Reboxetine	22/05/91	02/07/91	42	8	8	100.0	100.0		4	4	4
					15	0	0	100.0	100.0		0	0	0
					28	0	0	100.0	100.0	10e	0	0	0
4/3	99	Placebo	20/06/91	11/07/91	42	8	8	100.0	100.0		4	4	4
					22	8	4	50.0	97.8	1e	4	4	4
					4	8	3	100.0	98.1		4	4	4
4/3	100	Imipramine	17/07/91	21/07/91	5	10	10	100.0	98.4		4	4	6
					32	0	0	100.0	100.0		0	0	0
					7	0	0	100.0	100.0	6e	0	0	0
4/3	100	Imipramine	08/08/91	15/08/91	1	0	0	100.0	100.0		50	50	100
					8	100	100	100.0	100.0	9m	50	50	100
					2	150	150	100.0	100.0		50	50	100
					21								

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 8=start/end treatment in morning or evening, 9=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

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17

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
4/3	101	Imipramine	17/03/92	19/03/92	3	100	100	100.0	100.0		50	50	
			20/03/92	27/04/92	39	150	150	100.0	100.0		50	100	
					42								
4/4	109	Reboxetine	08/06/91	19/07/91	42	8	8	100.0	100.0		4	4	
					42								
110	Imipramine	15/06/91	17/06/91	3	100	100	100.0	100.0		50	50		
		18/06/91	26/07/91	39	150	150	100.0	100.0		50	100		
					42								
111	Imipramine	04/07/91	06/07/91	3	100	100	100.0	100.0		50	50		
		07/07/91	14/08/91	39	150	150	100.0	100.0		50	100		
					42								
112	Placebo	10/07/91	20/08/91	42	0	0	100.0	100.0		0	0		
				42									
113	Reboxetine	31/08/91	11/10/91	42	8	8	100.0	100.0		4	4		
				42									
114	Placebo	20/11/91	31/12/91	42	0	0	100.0	100.0		0	0		
				42									
175	Imipramine	13/02/92	15/02/92	3	100	100	100.0	100.0		50	50		
		16/02/92	25/03/92	39	150	150	100.0	100.0		50	100		
					42								
176	Placebo	14/03/92	07/04/92	25	0	0	100.0	100.0		0	0		
		08/04/92	08/04/92	1	0	0	100.0	100.0	6a	0	0		
					26								
177	Imipramine	28/04/92	30/04/92	3	100	100	100.0	100.0		50	50		
		01/05/92	11/05/92	11	150	150	100.0	100.0		50	100		

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(***) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

18

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (ng)	Daily dose (ng)	Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (ng)	Evening dose (ng)	Overdose (**)
4/4	178	Reboxetine	28/04/92	08/06/92	14	8	8	100.0	100.0		4	4	
					42								
	179	Placebo	11/09/92	28/09/92	18	0	0	100.0	100.0	6a	0	0	
					1								
	180	Reboxetine	07/10/92	17/11/92	19	8	8	100.0	100.0		4	4	
					42								
5/1	127	Reboxetine	06/06/91	26/06/91	21	8	8	100.0	100.0		4	4	
					21								
	128	Reboxetine	14/06/91	25/07/91	42	8	8	100.0	100.0		4	4	
					42								
	129	Placebo	24/12/91	03/02/92	42	0	0	100.0	100.0		0	0	
					42								
	130	Placebo	05/03/92	14/04/92	41	0	0	100.0	100.0	5a	0	0	
					1								
	131	Imipramine	21/03/92	23/03/92	3	100	100	100.0	100.0		50	50	
					38								
	132	Imipramine	25/06/92	27/06/92	3	100	100	100.0	100.0		50	50	
					40								

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

9550082

19

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Z	Compl. cumulat.	Reason (x)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
5/2	121	Imipramine	20/12/91	22/12/91	3	100	100	100.0		100.0		50	50	
			23/12/91	26/01/92	35	150	150	100.0		100.0		50	100	
			27/01/92	27/01/92	1	150	50	100.0		100.0	6e	50		
125	Reboxetine		28/01/91	23/02/91	27	8	8	100.0		100.0		4	4	
			24/02/91	24/02/91	1	8	4	50.0		98.2	1e	4	4	
			25/02/91	09/03/91	13	8	8	100.0		98.8		4	4	
			10/03/91	10/03/91	1	8	4	50.0		97.6	1e	4	4	
					42									
5/3	133	Placebo	29/11/91	12/12/91	14	0	0	100.0		100.0		0	0	
					14									
5/3	134	Reboxetine	06/12/91	16/01/92	42	8	8	100.0		100.0		4	4	
					42									
5/3	135	Imipramine	10/01/92	12/01/92	3	100	100	100.0		100.0		50	50	
			13/01/92	20/02/92	39	150	150	100.0		100.0		50	100	
					42									
136	Imipramine		02/03/92	04/03/92	3	100	100	100.0		100.0		50	50	
			05/03/92	07/03/92	3	150	150	100.0		100.0		50	100	
			08/03/92	08/03/92	1	150	50	33.3		90.5	10e	50	50	
			09/03/92	12/04/92	35	150	150	100.0		98.4		50	100	
137	Reboxetine		15/05/92	25/06/92	42	8	8	100.0		100.0		4	4	
					42									
138	Placebo		15/05/92	15/05/92	1	0	0	100.0		100.0		0	0	
			16/05/92	16/05/92	1	0	0	100.0		100.0	6e	0	0	

(x) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(xx) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

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20

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)													
6/1	151	Imipramine	21/01/92	21/01/92	1	100	50	100.0	100.0	9m	50	50														
														22/01/92	23/01/92	2	100	100.0	100.0	50	50					
														24/01/92	27/01/92	4	150	100.0	100.0	50	100					
														28/01/92	28/01/92	1	150	100.0	100.0	50	50					
152	Reboxetine	24/02/92	15/03/92	21	8	8	100.0	100.0	100.0	4	4	4														
														16/03/92	07/04/92	23	10	100.0	100.0	4	6					
153	Reboxetine	18/03/91	18/03/91	1	8	4	100.0	100.0	100.0	9m	4	4														
														19/03/91	28/04/91	41	8	100.0	100.0	4	4					
														29/04/91	29/04/91	1	8	100.0	100.0	4	4					
														44												
														43												
154	Imipramine	30/03/92	01/04/92	3	100	0	0.0	0.0	0.0	0	0	0														
														02/04/92	06/04/92	5	150	0.0	0.0	0	0					
155	Placebo	08/07/92	04/08/92	28	0	0	100.0	100.0	100.0	0	0	0														
														28												
156	Placebo	08/09/92	19/10/92	42	0	0	100.0	100.0	100.0	0	0	0														
														42												
6/2	Reboxetine	30/04/91	26/05/91	27	8	8	100.0	100.0	100.0	1e	4	4														
														27/05/91	27/05/91	1	8	50.0	98.2	4	4					
														28/05/91	10/06/91	14	8	100.0	98.8	4	4					
														42												
158	Imipramine	24/11/91	26/11/91	3	100	100	100.0	100.0	100.0	50	50	100														
														27/11/91	05/01/92	40	150	100.0	100.0	50	100					

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(xx) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
					43								
6/2	159	Imipramine	14/07/91	16/07/91	3	100	100	100.0	100.0		50	50	
			17/07/91	24/08/91	39	150	150	100.0	100.0		50	100	
					42								
160		Placebo	24/11/91	04/01/92	42	0	0	100.0	100.0		0	0	
					42								
161		Reboxetine	20/02/92	18/03/92	28	8	8	100.0	100.0		4	4	
					28								
162		Placebo	10/07/91	12/07/91	3	0	0	100.0	100.0		0	0	
			13/07/91	13/07/91	1	0	0	100.0	100.0	6e	0	0	
					4								
169		Imipramine	26/12/91	28/12/91	3	100	100	100.0	100.0		50	50	
			29/12/91	15/01/92	18	150	150	100.0	100.0		50	100	
					21								
170		Placebo	01/11/91	15/11/91	15	0	0	100.0	100.0		0	0	
					15								
171		Imipramine	22/07/92	24/07/92	3	100	100	100.0	100.0		50	50	
			25/07/92	01/09/92	39	150	150	100.0	100.0		50	100	
					42								
172		Reboxetine	07/07/92	17/08/92	42	8	8	100.0	100.0		4	4	
					42								
173		Placebo	05/07/92	15/08/92	42	0	0	100.0	100.0		0	0	
					42								

1000

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

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22

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Z	Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
6/2	174	Reboxetine	11/05/92	21/06/92	42	8	8	100.0	100.0	100.0		4	4	
					42									
6/3	163	Reboxetine	06/06/91	07/06/91	2	8	8	100.0	100.0	100.0		4	4	
			08/06/91	08/06/91	1	8	4	100.0	100.0	100.0	6a	4		
					3									
164		Imipramine	11/10/91	13/10/91	3	100	100	100.0	100.0	100.0		50	50	
			14/10/91	30/10/91	17	150	150	100.0	100.0	100.0		50	100	
			31/10/91	21/11/91	22	200	200	100.0	100.0	100.0		100	100	
					42									
165		Imipramine	16/10/91	18/10/91	3	100	100	100.0	100.0	100.0		50	50	
			19/10/91	05/11/91	18	150	150	100.0	100.0	100.0		50	100	
			06/11/91	25/11/91	20	200	200	100.0	100.0	100.0		100	100	
			26/11/91	26/11/91	1	200	100	100.0	100.0	100.0	5e	100		
					42									
166		Reboxetine	25/10/91	29/10/91	5	8	8	100.0	100.0	100.0		4	4	
					5									
167		Placebo	18/11/91	18/11/91	1	0	0	100.0	100.0	100.0		0	0	
			19/11/91	08/12/91	20	0	0	100.0	100.0	100.0	9n	0	0	
			09/12/91	09/12/91	1	0	0	100.0	100.0	100.0	10e	0	0	
			10/12/91	27/12/91	18	0	0	100.0	100.0	100.0		0	0	
					40									
168		Placebo	05/12/91	05/01/92	34	0	0	100.0	100.0	100.0		0	0	
			06/01/92	06/01/92	1	0	0	100.0	100.0	100.0	9e	0	0	
					35									
505		Imipramine	05/12/91	05/12/91	3	100	100	100.0	100.0	100.0		50	50	
			06/12/91	17/12/91	12	150	150	100.0	100.0	100.0		50	100	
					15									

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(xx) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
m = morning, e = evening

1001

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23

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Z Compl. day	X Compl. cumulat.	Reason (#)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
6/3	506	Placebo	08/01/92	08/01/92	1	0	0	100.0	100.0	9m	0	0	0
			09/01/92	19/02/92	42	0	0	100.0	100.0			0	0
43													
507	Imipramine	14/01/92	16/01/92	3	100	100	100.0	100.0	100.0		50	50	
		17/01/92	24/02/92	39	150	150	100.0	100.0	100.0		50	100	
42													
508	Reboxetine	05/02/92	04/03/92	29	8	8	100.0	100.0	100.0		4	4	
		05/03/92	17/03/92	13	10	10	100.0	100.0	100.0		4	6	
42													
509	Placebo	24/02/92	24/02/92	1	0	0	100.0	100.0	100.0	9m	0	0	
		25/02/92	06/04/92	42	0	0	100.0	100.0	100.0		0	0	
43													
510	Reboxetine	27/02/92	09/03/92	12	8	8	100.0	100.0	100.0		4	4	
		10/03/92	10/03/92	1	8	4	100.0	100.0	100.0	6e	4	4	
13													
511	Imipramine	19/03/92	21/03/92	3	100	100	100.0	100.0	100.0		50	50	
		22/03/92	21/04/92	31	150	150	100.0	100.0	100.0		50	100	
34													
512	Placebo	01/04/92	01/04/92	1	0	0	100.0	100.0	100.0	3e	0	0	
1													
513	Imipramine	13/05/92	15/05/92	3	100	100	100.0	100.0	100.0		50	50	
		16/05/92	23/06/92	39	150	150	100.0	100.0	100.0		50	100	
42													
7/02	181	Reboxetine	27/01/92	16/02/92	21	8	8	100.0	100.0		4	4	
			17/02/92	08/03/92	21	10	10	100.0	100.0	100.0		4	6

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(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
n = morning, e = evening

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24

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Σ Compl. cumulat.	Reason (#)	Morning dose (mg)	Evening dose (mg)	Overdose (**)											
7/02	182	Placebo	23/11/91	03/01/92	42	0	0	100.0	100.0		0	0	0											
														183	Imipramine	02/01/92	04/01/92	3	100	100.0	100.0	50	50	
																								05/01/92
16/01/92	18/01/92	3	150	0.0	82.4																			
184	Imipramine	27/01/92	29/01/92	3	100	100.0	100.0	100.0	100.0		50	50												
														30/01/92	08/03/92	39	150	100.0	100.0	50	100			
																						42		
185	Reboxetine	10/04/92	04/05/92	25	8	100.0	100.0	100.0	100.0	6e	4	4												
														05/05/92	05/05/92	1	8	100.0	100.0	4	4			
																						26		
186	Placebo	16/04/92	27/05/92	42	0	0	100.0	100.0	100.0		0	0												
														535	Placebo	15/04/92	26/05/92	42	0	0	100.0	100.0	0	0
536	Reboxetine	08/05/92	28/05/92	21	8	100.0	100.0	100.0	100.0		4	4												
														29/05/92	18/06/92	21	10	100.0	100.0	4	6			
																						42		
7/03	187	Imipramine	18/02/92	20/02/92	3	100	100.0	100.0	100.0		50	50												
														21/02/92	30/03/92	39	150	100.0	100.0	50	100			
																						42		
188	Placebo	25/02/92	06/04/92	42	0	0	100.0	100.0	100.0		0	0												

1003

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 m = morning, e = evening

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25

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
7/03	189	Placebo	25/02/92	06/04/92	42	0	0	100.0	100.0		0	0	0
					42								
	190	Reboxetine	28/02/92	09/04/92	42	8	8	100.0	100.0		4	4	4
					42								
	191	Imipramine	03/03/92	05/03/92	3	100	100	100.0	100.0		50	50	50
			06/03/92	10/04/92	36	150	150	100.0	100.0		50	100	100
					39								
	192	Reboxetine	10/03/92	20/04/92	42	8	8	100.0	100.0		4	4	4
					42								
	523	Reboxetine	06/05/92	16/06/92	42	8	8	100.0	100.0		4	4	4
					42								
	524	Placebo	06/05/92	16/06/92	42	0	0	100.0	100.0		0	0	0
					42								
	525	Placebo	06/05/92	16/06/92	42	0	0	100.0	100.0		0	0	0
					42								
	526	Reboxetine	06/05/92	16/06/92	42	8	8	100.0	100.0		4	4	4
					42								
	527	Imipramine	19/05/92	21/05/92	3	100	100	100.0	100.0		50	50	50
			22/05/92	08/06/92	18	150	150	100.0	100.0		50	100	100
			09/06/92	15/06/92	7	100	100	66.7	91.7	4a	50	100	100
			16/06/92	29/06/92	14	150	150	100.0	94.4		50	100	100
					42								

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(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
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1004

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26

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Z Compl. day	Z Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)	
7/03	528	Imipramine	19/05/92	21/05/92	3	100	0	0.0	0.0					
			22/05/92	25/05/92	4	150	0	0.0						
			26/05/92	22/06/92	28	150	100.0	80.0		50	100			
					35									
7/04	193	Placebo	25/01/92	06/03/92	42	0	0	100.0	100.0		0	0		
								42						
194	Reboxetine	Reboxetine	25/01/92	06/03/92	42	8	8	100.0	100.0		4	4		
								42						
195	Placebo	Placebo	25/01/92	06/03/92	42	0	0	100.0	100.0		0	0		
								42						
196	Reboxetine	Reboxetine	01/02/92	21/02/92	21	8	8	100.0	100.0		4	4		
			22/02/92	28/02/92	7	8	100.0	100.0		4	4			
			29/02/92	05/03/92	6	8	100.0	100.0		4	4			
			06/03/92	06/03/92	1	8	4	56.0	98.6	10e	4	4		
			07/03/92	13/03/92	7	8	8	100.0	98.8		4	4		
								42						
197	Imipramine	Imipramine	01/02/92	03/02/92	3	100	100	100.0	100.0		50	50		
			04/02/92	21/02/92	18	150	100	100.0	100.0		50	100		
			22/02/92	13/03/92	21	200	200	100.0	100.0		100	100		
					42									
198	Imipramine	Imipramine	01/02/92	03/02/92	3	100	100	100.0	100.0		50	50		
			04/02/92	13/03/92	39	150	150	100.0	100.0		50	100		
					42									
199	Imipramine	Imipramine	28/03/92	30/03/92	3	100	100	100.0	100.0		50	50		
			31/03/92	17/04/92	18	150	150	100.0	100.0		50	100		
			18/04/92	04/05/92	17	200	200	100.0	100.0		100	100		
			05/05/92	05/05/92	1	200	100	50.0	98.7	1m	100	100		
			06/05/92	08/05/92	3	200	200	100.0	98.8		100	100		
					42									

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(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
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27

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (x)												
7/04	200	Placebo	28/03/92	08/05/92	42	0	0	100.0	100.0		0	0	0												
														201	Reboxetine	28/03/92	27/04/92	31	8	100.0	100.0		4	4	
																28/04/92	28/04/92	1	8	0.0	96.9	1m 1e	4	4	
202	Reboxetine	29/04/92	08/05/92	10	8	100.0	97.6		4	4															
		04/04/92	24/04/92	21	8	100.0	100.0		4	4															
		25/04/92	27/04/92	3	10	100.0	100.0		4	6															
203	Placebo	28/04/92	28/04/92	1	10	4	40.0	97.6	1e	4	4														
		29/04/92	15/05/92	17	10	100.0	96.6		4	6															
		04/04/92	21/04/92	18	0	100.0	100.0		0	0															
204	Imipramine	23/04/92	22/04/92	1	0	0	100.0	100.0	1m	0	0														
		04/04/92	06/04/92	3	100	100.0	100.0		50	50															
		07/04/92	24/04/92	18	150	100.0	100.0		50	100															
205	Placebo	25/04/92	29/04/92	5	200	200	100.0	100.0		100	100														
		30/04/92	30/04/92	1	200	100	50.0	98.1	1m	100	100														
		01/05/92	15/05/92	15	200	200	100.0	98.8		100	100														
7/05	205	Placebo	27/01/92	16/02/92	21	0	0	100.0	100.0		0	0	0												
														206	Imipramine	17/02/92	08/03/92	21	0	100.0	100.0		0	0	
																28/01/92	30/01/92	3	100	100.0	100.0		50	50	
206	Imipramine	31/01/92	09/03/92	39	150	150	100.0	100.0		50	100														

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 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
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23

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily Dose (mg)	Compl. day	Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
7/05	207	Imipramine	28/01/92	30/01/92	3	100	100	100.0	100.0		50	50	
			31/01/92	09/03/92	39	150	150	100.0	100.0		50	100	
					42								
	208	Reboxetine	30/01/92	11/03/92	42	8	8	100.0	100.0		4	4	
					42								
	209	Placebo	05/02/92	17/03/92	42	0	0	100.0	100.0		0	0	
					42								
	210	Reboxetine	07/02/92	19/03/92	42	8	8	100.0	100.0		4	4	
					42								
	541	Reboxetine	17/03/92	27/04/92	42	8	8	100.0	100.0		4	4	
					42								
	542	Imipramine	17/03/92	19/03/92	3	100	100	100.0	100.0		50	50	
			20/03/92	27/04/92	39	150	150	100.0	100.0		50	100	
					42								
	543	Imipramine	18/03/92	20/03/92	3	100	100	100.0	100.0		50	50	
			21/03/92	28/04/92	39	150	150	100.0	100.0		50	100	
					42								
	544	Placebo	24/03/92	04/05/92	42	0	0	100.0	100.0		0	0	
					42								
	545	Placebo	25/03/92	05/05/92	42	0	0	100.0	100.0		0	0	
					42								
	546	Reboxetine	25/03/92	05/05/92	42	8	8	100.0	100.0		4	4	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

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29

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
7/07	529	Placebo	18/02/92	30/03/92	42	0	0	100.0	100.0		0	0	0
					42								
					42								
530	Imipramine	20/02/92	22/02/92	3	100	100	100.0	100.0			50	50	
		23/02/92	04/03/92	11	150	150	100.0	100.0			50	100	
		05/03/92	11/03/92	7	150		0.0	66.7					
531	Reboxetine	24/02/92	26/03/92	30	8	8	100.0	100.0			4	4	
		25/03/92	25/03/92	1	8	4	50.0	98.4	1m		4	4	
		26/03/92	05/04/92	11	8	8	100.0	98.8			4	4	
532	Imipramine	27/04/92	29/04/92	3	100	100	100.0	100.0			50	50	
		30/04/92	07/06/92	39	150	150	100.0	100.0			50	100	
		42											
533	Reboxetine	04/05/92	24/05/92	21	8	8	100.0	100.0			4	4	
		25/05/92	14/06/92	21	10	10	100.0	100.0			4	6	
		42											
534	Placebo	15/05/92	25/06/92	42	0	0	100.0	100.0			0	0	
		42											
		42											
8	211	Reboxetine	13/05/91	26/05/91	14	8	8	100.0	100.0		4	4	
			14										
			42										
212	Placebo	14/09/91	25/10/91	42	0	0	100.0	100.0			0	0	
		42											
		42											
213	Imipramine	22/11/91	24/11/91	3	100	100	100.0	100.0			50	50	
		42											
		42											

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 8=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

1008

9550082

30

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
8	214	Reboxetine	23/11/91	03/01/92	3	8	8	100.0	100.0	0	4	4	
					42								
	215	Placebo	18/02/92	30/03/92	42	0	0	100.0	100.0	0	0	0	
					42								
	216	Imipramine	27/03/92	29/03/92	3	100	100	100.0	100.0	0	50	50	
					18								
					21								
	217	Reboxetine	30/03/92	10/05/92	42	8	8	100.0	100.0	0	4	4	
					42								
	218	Reboxetine	09/04/92	20/05/92	42	8	8	100.0	100.0	0	4	4	
					42								
	219	Placebo	11/04/92	01/05/92	21	0	0	100.0	100.0	0	0	0	
					21								
	220	Imipramine	27/04/92	29/04/92	3	100	100	100.0	100.0	0	50	50	
					39								
	221	Imipramine	28/04/92	30/04/92	3	100	100	100.0	100.0	0	50	50	
					39								
	222	Placebo	28/04/92	08/06/92	42	0	0	100.0	100.0	0	0	0	
					42								

1009

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

31

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RD
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	% Compl.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
8	223	Imipramine	11/05/92	13/05/92	3	100	100	100.0	100.0		50	50	
			14/05/92	21/06/92	39	150	150	100.0	100.0		50	100	
					42								
224	224	Placebo	07/09/92	18/10/92	42	0	0	100.0	100.0		0	0	
					42								
225	225	Placebo	11/09/92	22/10/92	42	0	0	100.0	100.0		0	0	
					42								
226	226	Reboxetine	23/09/92	13/10/92	21	8	8	100.0	100.0		4	4	
			14/10/92	03/11/92	21	10	10	100.0	100.0		4	5	
					42								
227	227	Reboxetine	25/09/92	15/10/92	21	8	8	100.0	100.0		4	4	
			16/10/92	05/11/92	21	10	10	100.0	100.0		4	6	
					42								
228	228	Imipramine	26/09/92	28/09/92	3	100	100	100.0	100.0		50	50	
			29/09/92	02/10/92	4	150	150	100.0	100.0		50	100	
					7								
229	229	Imipramine	30/09/92	02/10/92	3	100	100	100.0	100.0		50	50	
			03/10/92	20/10/92	18	150	150	100.0	100.0		50	100	
			21/10/92	10/11/92	21	200	200	100.0	100.0		100	100	
					42								
230	230	Reboxetine	28/09/92	18/10/92	21	8	8	100.0	100.0		4	4	
			19/10/92	08/11/92	21	10	10	100.0	100.0		4	6	
					42								
231	231	Imipramine	30/09/92	02/10/92	3	100	100	100.0	100.0		50	50	
			03/10/92	20/10/92	18	150	150	100.0	100.0		50	100	
			21/10/92	10/11/92	21	200	200	100.0	100.0		100	100	

1010

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

9550082

32

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
8	232	Reboxetine	02/10/92	22/10/92	21	8	8	100.0	100.0		4	4	
			23/10/92	12/11/92	21	10	10	100.0	100.0		4	6	
					42								
233		Placebo	07/10/92	17/11/92	42	0	0	100.0	100.0		0	0	
					42								
234		Placebo	07/10/92	17/11/92	42	0	0	100.0	100.0		0	0	
					42								
8/A	235	Placebo	14/10/92	24/11/92	42	0	0	100.0	100.0		0	0	
					42								
236		Placebo	14/10/92	24/11/92	42	0	0	100.0	100.0		0	0	
					42								
237		Reboxetine	14/10/92	24/11/92	42	8	8	100.0	100.0		4	4	
					42								
238		Reboxetine	14/10/92	24/11/92	42	8	8	100.0	100.0		4	4	
					42								
239		Imipramine	16/10/92	18/10/92	3	100	100	100.0	100.0		50	50	
			19/10/92	05/11/92	18	150	150	100.0	100.0		50	100	
			06/11/92	26/11/92	21	200	200	100.0	100.0		100	100	
					42								
240		Imipramine	16/10/92	18/10/92	3	100	100	100.0	100.0		50	50	
			19/10/92	05/11/92	18	150	150	100.0	100.0		50	100	
			06/11/92	26/11/92	21	200	200	100.0	100.0		100	100	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=stat/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

1011

9550082

33

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Contro	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
8/A	553	Placebo	16/10/92	26/11/92	42	0	0	100.0	100.0		0	0	
					42								
	554	Reboxetine	16/10/92	26/11/92	42	8	8	100.0	100.0		4	4	
					42								
	555	Reboxetine	16/10/92	26/11/92	42	8	8	100.0	100.0		4	4	
					42								
	556	Imipramine	16/10/92	18/10/92	3	100	100	100.0	100.0		50	50	
			19/10/92	28/11/92	39	150	150	100.0	100.0		50	100	
					42								
9	241	Placebo	07/02/91	17/02/91	11	0	0	100.0	100.0		0	0	
					11								
	242	Reboxetine	18/02/91	10/03/91	21	8	8	100.0	100.0		4	4	
			11/03/91	11/03/91	1	8	4	100.0	100.0	6e	4	4	
					22								
	243	Reboxetine	20/02/91	01/03/91	10	8	8	100.0	100.0		4	4	
			02/03/91	03/03/91	2	8	12	100.0	100.0		8	4	
			04/03/91	05/03/91	2	8	8	100.0	100.0		4	4	
			06/03/91	06/03/91	1	8	4	100.0	100.0	6e	4	4	
					15								(B - m)
	244	Imipramine	19/02/91	21/02/91	3	100	100	100.0	100.0		50	50	
			22/02/91	11/03/91	18	150	150	100.0	100.0		50	100	
			12/03/91	12/03/91	1	200	150	100.0	100.0		50	100	
			13/03/91	13/03/91	1	200	100	100.0	100.0	6e	100	100	
					23								

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
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9550082

34

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.6

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
9	245	Imipramine	22/02/91	24/02/91	3	100	100	100.0	100.0		50	50	
			25/02/91	04/04/91	39	150	150	100.0	100.0		50	100	
					42								
	246	Placebo	22/02/91	17/03/91	24	0	0	100.0	100.0		0	0	
					24								
	247	Placebo	25/02/91	25/03/91	29	0	0	100.0	100.0		0	0	
			26/03/91	26/03/91	1	0	0	100.0	100.0	6e	0	0	
					30								
	248	Placebo	07/03/91	07/03/91	1	0	0	100.0	100.0	9m	0	0	
			08/03/91	21/03/91	14	0	0	100.0	100.0		0	0	
					15								
	249	Reboxetine	08/03/91	10/03/91	3	8	8	100.0	100.0		4	4	
			11/03/91	17/03/91	1	8	4	100.0	100.0	6e	4	4	
					4								
	250	Imipramine	12/03/91	14/03/91	3	100	100	100.0	100.0		50	50	
			15/03/91	01/04/91	18	150	150	100.0	100.0		50	100	
			02/04/91	02/04/91	1	200	150	100.0	100.0		50	100	
			03/04/91	07/04/91	5	200	200	100.0	100.0	6e	100	100	
			08/04/91	08/04/91	1	200	100	100.0	100.0		100		
					28								
	251	Imipramine	20/03/91	22/03/91	3	100	100	100.0	100.0		50	50	
			23/03/91	11/04/91	20	150	150	100.0	100.0		50	100	
			12/04/91	12/04/91	1	150	50	100.0	100.0	6e	50	50	
					24								
	252	Reboxetine	02/04/91	17/04/91	16	8	8	100.0	100.0		4	4	
			18/04/91	20/04/91	3	8	4	100.0	100.0	3e	4	4	
					19								

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(xx) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

35

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	X Compl. day	X Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)	
9	253	Reboxetine	02/04/91	07/04/91	6	8	8	100.0	100.0		4	4		
			08/04/91	08/04/91	1	8	4	100.0	100.0	6e	4			
					7									
	254	Imipramine	09/04/91	11/04/91	3	100	100	100.0	100.0			50	50	
			12/04/91	15/04/91	4	150	150	100.0	100.0		50	100		
			16/04/91	16/04/91	1	150	50	100.0	100.0	6e	50			
					8									
255	Reboxetine	13/05/91	05/06/91	24	8	8	100.0	100.0		4	4			
		06/06/91	06/06/91	1	8	4	100.0	100.0	6e	4				
				25										
256	Imipramine	27/05/91	29/05/91	3	100	100	100.0	100.0			50	50		
		30/05/91	05/06/91	7	150	150	100.0	100.0		50	100			
		06/06/91	09/06/91	4	150	50	100.0	100.0	3e	50				
		10/06/91	10/06/91	1	150	50	100.0	100.0	3e	50				
		11/06/91	16/06/91	6	150	50	100.0	100.0	3e	50				
		17/06/91	20/06/91	4	150	150	100.0	100.0		50	100			
		21/06/91	08/07/91	18	150	50	100.0	100.0	3e	50				
				43										
		257	Placebo	25/06/91	30/06/91	6	0	0	100.0	100.0		0	0	
				01/07/91	01/07/91	1	0	0	100.0	100.0	6e	0		
				7										
258	Placebo	01/07/91	09/07/91	9	0	0	100.0	100.0		0	0			
		10/07/91	10/07/91	1	0	0	100.0	100.0	6e	0				
				10										
11	319	Placebo	02/08/91	12/09/91	42	0	0	100.0	100.0		0	0		
					42									
320	Imipramine	17/08/91	19/08/91	3	100	100	100.0	100.0			50	50		
		20/08/91	27/08/91	8	150	150	100.0	100.0		50	100			
		28/08/91	28/08/91	1	150	100	66.7	97.2	1m					

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

1014

9550082

36

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% compl. day	% compl. cumulat.	Reason (*)	Morning dose (ng)	Evening dose (ng)	Overdose (**)	
11	320	Imipramine	29/08/91	01/09/91	4	150	150	100.0	97.9		50	100		
			02/09/91	02/09/91	1	150	50	33.3	94.1	4e	50			
			03/09/91	03/09/91	1	200	100	50.0	91.7	4m	100	100		
			04/09/91	25/09/91	22	200	200	100.0	96.3	9e	100			
	26/09/91	26/09/91	1	200	100	50.0	96.3							
	41													
	321	Placebo	06/09/91	16/10/91	41	0	0	100.0	100.0	9e	0	0		
			17/10/91	17/10/91	1	0	0	100.0	100.0					
	322	Reboxetine	27/09/91	16/10/91	20	8	8	100.0	100.0			4	4	
			17/10/91	06/11/91	21	10	10	100.0	100.0			4	6	
			07/11/91	07/11/91	1	10	4	40.0	100.0	9e		4		
42														
15/11/91			25/12/91	41	8	8	100.0	100.0	9e		4	4		
26/12/91	26/12/91	1	8	4	40.0	100.0			4					
324	Imipramine	06/12/91	08/12/91	3	100	100	100.0	100.0			50	50		
		09/12/91	26/12/91	18	150	150	100.0	100.0			50	100		
		27/12/91	27/12/91	1	200	150	75.0	100.0			50	100		
		28/12/91	15/01/92	19	200	200	100.0	100.0			100	100		
	16/01/92	16/01/92	1	200	100	50.0	100.0	9e		100				
	42													
	325	Reboxetine	13/12/91	18/12/91	6	8	8	100.0	100.0			4	4	
			19/12/91	19/12/91	1	8	4	50.0	92.9	10e		4		
			20/12/91	26/12/91	7	8	8	100.0	96.4			4	4	
			27/12/91	27/12/91	1	8	4	50.0	93.3	1e		4		
			28/12/91	22/01/92	26	8	8	100.0	97.6			4	4	
23/01/92			23/01/92	1	8	4	50.0	97.6	9e		4			
42														
326	Placebo	16/01/92	16/01/92	1	0	0	100.0	100.0	9m		0	0		
		17/01/92	20/02/92	35	0	0	100.0	100.0			0	0		

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 8=double low dose, C=high daily dose in one administration, 0=low daily dose in one administration
 m = morning, e = evening

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

37

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	X Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
11	326	Placebo	21/02/92	21/02/92	1	0	0	100.0	100.0	10m 10e	0	0	0
			22/02/92	26/02/92	5	0	0	100.0	100.0				
			27/02/92	27/02/92	1	0	0	100.0	100.0				
					43								
327	Imipramine		30/01/92	01/02/92	3	100	100	100.0	100.0		50	50	
			02/02/92	04/02/92	3	150	150	100.0	100.0		50	100	
			05/02/92	05/02/92	1	150	50	100.0	100.0	6e	50		
					7								
328	Imipramine		31/01/92	02/02/92	3	100	100	100.0	100.0		50	50	
			03/02/92	04/02/92	2	150	150	100.0	100.0		50	100	
			05/02/92	05/02/92	1	150	100.0	100.0	3m 6e				
					6								
329	Placebo		10/04/92	20/05/92	41	0	0	100.0	100.0		0	0	
			21/05/92	21/05/92	1	0	0	100.0	100.0	9e	0	0	
								42					
330	Reboxetine		09/04/92	09/04/92	1	8	4	100.0	100.0	9m		4	
			10/04/92	29/04/92	20	8	8	100.0	100.0		4	4	
			30/04/92	13/05/92	14	10	10	100.0	100.0		4	6	
			14/05/92	14/05/92	1	10	4	50.0	98.6	1e	4	4	
			15/05/92	16/05/92	2	10	10	100.0	98.7		4	6	
			17/05/92	17/05/92	1	10	4	40.0	97.2	1e	4	4	
			18/05/92	20/05/92	3	10	10	100.0	97.4		4	6	
					43								
331	Imipramine		17/04/92	19/04/92	3	100	100	100.0	100.0		50	50	
			20/04/92	27/05/92	38	150	150	100.0	100.0		50	100	
			28/05/92	28/05/92	1	150	50	100.0	100.0	9e	50		
					42								
332	Reboxetine		19/05/92	28/06/92	41	8	8	100.0	100.0		4	4	
			29/06/92	29/06/92	1	8	4	100.0	100.0	9e	4	4	

1016

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(xx) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
n = morning, e = evening

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38

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
11	333	Placebo	27/05/92 07/07/92	06/07/92 07/07/92	42	0	0	100.0	100.0	9e	0	0	
					41	0	0	100.0	100.0				
					1	0	0	100.0	100.0				
					42								
334	Reboxetine	29/05/92 01/06/92	31/05/92 01/06/92	3	8	8	100.0	100.0	3m 6e	4	4		
				1	8	8	100.0	100.0					
				4									
				4									
335	Placebo	03/06/92 14/07/92	13/07/92 14/07/92	41	0	0	100.0	100.0	9e	0	0		
				1	0	0	100.0	100.0					
				42									
				4									
336	Imipramine	18/06/92 19/06/92 21/06/92 23/06/92	18/06/92 20/06/92 24/06/92 25/06/92	1	100	50	100.0	100.0	9m	50	50		
				2	100	100	100.0	100.0		50	100		
				4	150	150	100.0	100.0	6e	50	50		
				1	150	50	100.0	100.0		50			
				8									
				42									
337	Reboxetine	02/07/92 03/07/92 16/07/92 17/07/92 23/07/92 13/08/92	02/07/92 15/07/92 16/07/92 22/07/92 12/08/92 13/08/92	1	8	4	100.0	100.0	9m	4	4		
				13	8	8	100.0	100.0		4	4		
				1	8	4	50.0	96.7	1m	4	4		
				6	8	8	100.0	97.6		4	4		
				21	10	10	100.0	98.8		4	6		
				1	10	4	100.0	98.8	9e	4	4		
338	Imipramine	23/07/92 24/07/92 26/07/92 30/07/92	23/07/92 25/07/92 29/07/92 30/07/92	1	100	50	100.0	100.0	9m	50	50		
				2	100	100	100.0	100.0		50	100		
				4	150	150	100.0	100.0	6e	50	50		
				1	150	50	100.0	100.0		50			
367	Reboxetine	20/12/91 21/12/91	20/12/91 30/01/92	1	8	4	100.0	100.0	9m	4	4		
				41	8	8	100.0	100.0		4	4		
				8									
				8									

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
n = morning, e = evening

1017

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39

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Z Compl. day	X Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
12	368	Placebo	24/12/91	24/12/91	1	0	0	100.0	100.0	9m	0	0	0
			25/12/91	03/02/92	41	0	0	100.0	100.0			0	0
369	Imipramine	23/04/92	25/04/92	3	100	100	100.0	100.0	100.0		50	50	
		26/04/92	12/05/92	17	150	150	100.0	100.0	100.0		50	100	
		13/05/92	13/05/92	1	150	50	100.0	100.0	100.0	6e	50		
				21									
370	Placebo	29/04/92	19/05/92	21	0	0	100.0	100.0	100.0	6e	0	0	
		20/05/92	20/05/92	1	0	0	100.0	100.0	100.0		0		
371	Imipramine	01/05/92	03/05/92	3	100	100	100.0	100.0	100.0		50	50	
		04/05/92	06/05/92	3	150	150	100.0	100.0	100.0		50	100	
				6									
372	Reboxetine	02/06/92	02/06/92	1	8	4	100.0	100.0	100.0	9m	4	4	
		03/06/92	13/07/92	41	8	8	100.0	100.0	100.0		4	4	
373	Reboxetine	05/06/92	05/06/92	1	8	4	100.0	100.0	100.0	9m	4	4	
		06/06/92	29/06/92	24	8	8	100.0	100.0	100.0		4	4	
		30/06/92	02/07/92	3	8	10	100.0	100.0	100.0		4	6	
		03/07/92	13/07/92	11	10	10	100.0	100.0	100.0		4	6	
		14/07/92	14/07/92	1	10	4	100.0	100.0	100.0	6e	4	4	
374	Placebo	09/06/92	05/07/92	27	0	0	100.0	100.0	100.0	6e	0	0	
		06/07/92	06/07/92	1	0	0	100.0	100.0	100.0		0		
375	Imipramine	17/06/92	17/06/92	1	100	100	100.0	100.0	100.0		50	50	
				28									

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=stat/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
m = morning, e = evening

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40

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	X Compl. day	X Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (**)	
12	375	Imipramine	18/06/92	19/06/92	1	100	50	100.0	100.0	6e	50			
					2									
13	13	Placebo	13/04/91	24/05/91	42	0	0	100.0	100.0		0	0	0	
					42									
14	14	Placebo	02/07/91	22/07/91	21	0	0	100.0	100.0		0	0	0	
					1	0	0	100.0	100.0	1a	0	0	0	
					21	0	0	100.0	100.0		0	0	0	
					43									
15	15	Imipramine	05/07/91	07/07/91	3	100	100	100.0	100.0		50	50		
					24	150	150	100.0	100.0		50	100		
					1	200	150	100.0	100.0		50	100		
					14	200	200	100.0	100.0		100	100		
					42									
					3	100	100	100.0	100.0		50	50		
16	16	Imipramine	03/12/91	05/12/91	3	100	100	100.0	100.0		50	50		
					10	150	100.0	100.0	3m 3e	50	100			
					25	150	100.0	100.0		50	100			
					7	200	100.0	100.0		100	100			
					45									
17	17	Reboxetine	21/05/92	01/06/92	12	8	8	100.0	100.0		4	4		
					1	8	4	50.0	96.2		4	4		
					8	8	8	100.0	97.6	10a	4	4		
					6	10	10	100.0	98.1		4	6		
					7	10	0.0	77.9		4	6			
					8	10	100.0	82.1		4	6			
					42									
					19	8	8	100.0	100.0		4	4		
18	18	Reboxetine	24/06/92	12/07/92	21	10	10	100.0	100.0		4	6		
					40									
409	409	Reboxetine	10/12/91	20/12/91	11	8	8	100.0	100.0		4	4		
					40									

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(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
m = morning, e = evening

9550082

41

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	% Compl. cumulat.	Reason (%)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
13	409	Reboxetine	21/12/91	23/12/91	3	8	8	0.0	78.6	4m 4e	4	4	
			24/12/91	20/01/92	28	8	8	100.0	92.9				
					42								
410	Placebo	14/02/92	20/02/92	7	0	0	100.0	100.0			0	0	
		21/02/92	21/02/92	1	0	0	100.0	100.0	10m 10e		0	0	
		22/02/92	26/03/92	34	0	0	100.0	100.0			0	0	
				42									
411	Imipramine	28/03/92	30/03/92	3	100	100	100.0	100.0			50	50	
		31/03/92	17/04/92	18	150	150	100.0	100.0			50	100	
		18/04/92	08/05/92	21	200	200	100.0	100.0			100	100	
				42									
423	Placebo	14/09/92	27/10/92	44	0	0	100.0	100.0		0	0		
				44									
14	19	Reboxetine	10/04/92	06/05/92	27	8	8	100.0	100.0		4	4	
				27									
20	Imipramine	29/04/92	29/04/92	1	100	100	100.0	100.0			50	50	
		30/04/92	30/04/92	1	100	100	100.0	100.0	3m 3e		50	50	
		01/05/92	01/05/92	1	100	100	100.0	100.0			50	50	
		02/05/92	09/06/92	39	150	150	100.0	100.0			50	100	
				42									
21	Imipramine	20/07/92	20/07/92	1	100	50	100.0	100.0		9m	50	50	
		21/07/92	22/07/92	2	100	100	100.0	100.0			50	50	
		23/07/92	10/08/92	19	150	150	100.0	100.0			50	100	
		11/08/92	16/08/92	6	150	200	100.0	100.0			100	100	
		17/08/92	22/08/92	6	200	200	100.0	100.0			100	100	
		23/08/92	23/08/92	1	200	100	50.0	98.6		4m	100	100	
		42							6e				
				36									
15	25	Reboxetine	18/06/91	18/06/91	1	8	4	100.0	100.0	9m	4	4	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
m = morning, e = evening

1020

9550082

42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Z Compl. day	X Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
15	25	Reboxetine	19/06/91	29/07/91	41	8	8	100.0	100.0		4	4	
					42								
26		Placebo	20/06/91	20/06/91	1	0	0	100.0	100.0	9m	0	0	
			21/06/91	26/06/91	6	0	0	100.0	100.0		0	0	
			27/06/91	27/06/91	1	0	0	100.0	100.0	1m	0	0	
			28/06/91	31/07/91	34	0	0	100.0	100.0		0	0	
			01/08/91	01/08/91	1	0	0	100.0	100.0	9e	0	0	
					43								
27		Imipramine	02/07/91	04/07/91	3	100	100	100.0	100.0		50	50	
			05/07/91	29/07/91	25	150	150	100.0	100.0		50	100	
			30/07/91	30/07/91	1	50	50	33.3	97.7	1e	50	50	
			31/07/91	12/08/91	13	150	150	100.0	98.4		50	100	
			13/08/91	13/08/91	1	150	50	100.0	98.4	9e	50	50	
					43								
28		Reboxetine	08/08/91	09/09/91	33	8	8	100.0	100.0		4	4	
			10/09/91	10/09/91	1	8	4	50.0	98.5	1m	4	4	
			11/09/91	19/09/91	9	8	8	100.0	98.8		4	4	
					43								
29		Placebo	29/08/91	29/08/91	1	0	0	100.0	100.0	9m	0	0	
			30/08/91	18/09/91	20	0	0	100.0	100.0		0	0	
			19/09/91	19/09/91	1	0	0	100.0	100.0	6e	0	0	
					22								
30		Imipramine	03/09/91	05/09/91	3	100	100	100.0	100.0		50	50	
			06/09/91	07/09/91	2	150	150	100.0	100.0		50	100	
			08/09/91	08/09/91	1	150	50	33.3	88.9	10e	50	50	
			09/09/91	09/09/91	1	150	100	66.7	85.7	10m	100	100	
			10/09/91	23/09/91	14	150	150	100.0	95.2		50	100	
			24/09/91	24/09/91	1	150	100	66.7	93.9	10m	100	100	
			25/09/91	25/09/91	1	150	150	100.0	94.2		50	100	
			26/09/91	26/09/91	1	150	50	33.3	91.7	10e	50	50	
			27/09/91	07/10/91	11	150	150	100.0	94.3		50	100	
			08/10/91	08/10/91	1	150	50	33.3	92.5	1e	50	50	
			09/10/91	14/10/91	6	150	150	100.0	93.7		50	100	

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 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

1021

9550082

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43

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Z Compl. day	X Compl. cumulat.	Reason (#)	Morning doses (mg)	Evening doses (mg)	Overdose (x)										
15	30	Imipramine	15/10/91	15/10/91	1	150	50	100.0	99.8	9e	50	50											
														43									
403	Imipramine	04/10/91	04/10/91	1	100	50	100.0	100.0	100.0	9m	50	50											
		05/10/91	06/10/91	2	100	100	100.0	100.0	100.0	9m	50	50											
		07/10/91	13/11/91	38	150	150	100.0	100.0	100.0	9e	50	100											
		14/11/91	14/11/91	1	150	50	100.0	100.0	100.0	9e	50												
		42																					
		404	Reboxetine	08/10/91	08/10/91	1	8	4	100.0	100.0	100.0	9m	4	4									
				09/10/91	17/10/91	9	8	8	100.0	100.0	100.0	9m	4	4									
				18/10/91	18/10/91	1	8	4	50.0	95.5	10e	4	4										
				19/10/91	22/10/91	4	8	8	100.0	94.7	10e	4	4										
				23/10/91	23/10/91	1	8	4	50.0	93.8	10e	4	4										
24/10/91	30/10/91			7	8	8	100.0	95.7	10e	4	4												
31/10/91	31/10/91			1	8	4	50.0	95.8	10e	4	4												
01/11/91	04/11/91			4	8	8	100.0	94.6	6e	4	4												
05/11/91	05/11/91			1	8	4	100.0	94.8	6e	4	4												
29																							
405	Placebo	11/11/91	11/11/91	1	0	0	100.0	100.0	100.0	9m	0	0											
		12/11/91	22/12/91	41	0	0	100.0	100.0	100.0	9e	0	0											
		23/12/91	23/12/91	1	0	0	100.0	100.0	100.0	9e	0	0											
43																							
406	Imipramine	27/11/91	27/11/91	1	100	50	100.0	100.0	100.0	9m	50	50											
		28/11/91	29/11/91	2	100	100	100.0	100.0	100.0	9e	50	100											
		30/11/91	06/01/92	38	150	150	100.0	100.0	100.0	9e	50	100											
		07/01/92	07/01/92	1	150	50	100.0	100.0	100.0	9e	50												
		42																					
		407	Reboxetine	03/12/91	03/12/91	1	8	4	100.0	100.0	100.0	9m	4	4									
04/12/91	25/12/91			22	8	8	100.0	100.0	100.0	9m	4	4											
26/12/91	26/12/91			1	8	4	50.0	97.9	10m	4	4												
27/12/91	10/01/92			15	8	8	100.0	94.7	10m	4	4												
11/01/92	11/01/92			1	8	8	100.0	98.6	1m	4	4												
12/01/92	13/01/92			2	8	8	100.0	98.8	1m	4	4												
14/01/92	14/01/92			1	8	4	100.0	98.8	9e	4	4												
42																							

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
m = morning, e = evening

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44

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	Compl. day	Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
43													
15	408	Placebo	20/01/92	20/01/92	1	0	0	100.0	100.0	9m	0	0	
			21/01/92	03/03/92	43	0	0	100.0	100.0		0	0	
			04/03/92	04/03/92	1	0	0	100.0	100.0	9e	0	0	
45													
418		Placebo	30/01/92	30/01/92	1	0	0	100.0	100.0	9m	0	0	
			31/01/92	11/03/92	41	0	0	100.0	100.0		0	0	
			12/03/92	12/03/92	1	0	0	100.0	100.0	9e	0	0	
43													
419		Placebo	28/04/92	28/04/92	1	0	0	100.0	100.0	9m	0	0	
			29/04/92	01/05/92	3	0	0	100.0	100.0		0	0	
			02/05/92	02/05/92	1	0	0	100.0	100.0	1e	0	0	
			03/05/92	27/05/92	25	0	0	100.0	100.0		0	0	
			28/05/92	28/05/92	1	0	0	100.0	100.0	1m	0	0	
			29/05/92	29/05/92	1	0	0	100.0	100.0		0	0	
			30/05/92	30/05/92	1	0	0	100.0	100.0	1e	0	0	
			31/05/92	08/06/92	9	0	0	100.0	100.0		0	0	
			09/06/92	09/06/92	1	0	0	100.0	100.0	9e	0	0	

1023

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

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1

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	Z Cumpl. day	Z Compl. cumulat. Cps	Morning Cps	Afternoon Cps	Reason (%)	Overdose (%)
1	1	Imipramine	10/04/91	10/04/91	1	2	1	100.0	100.0	0	1	9m	
			11/04/91	28/04/91	18	2	2	100.0	100.0	1	1		
			29/04/91	29/04/91	1	2	1	50.0	97.5	1	1	1e	
			30/04/91	09/05/91	10	2	2	100.0	98.3	1	1	10m 10a	
			10/05/91	10/05/91	1	2	2	0.0	95.2	1	1		
			11/05/91	11/05/91	1	2	2	100.0	95.3	1	1	10e	
			12/05/91	13/05/91	2	2	1	50.0	94.0	1	1		
			14/05/91	21/05/91	8	2	2	100.0	94.0	1	1		
			22/05/91	22/05/91	1	2	1	100.0	94.2	1	0	9e	
							43						
2	Reboxetine	15/04/91	15/04/91	1	2	1	100.0	100.0	0	1	9m		
		16/04/91	26/05/91	41	2	2	100.0	100.0	1	1			
		27/05/91	27/05/91	1	2	1	100.0	100.0	1	0	9e		
						43							
3	Imipramine	06/05/91	06/05/91	1	2	1	100.0	100.0	0	1	9m		
		07/05/91	16/06/91	41	2	2	100.0	100.0	1	1			
						42							
						43							
4	Placebo	04/06/91	04/06/91	1	2	1	100.0	100.0	0	1	9m		
		05/06/91	15/07/91	41	2	2	100.0	100.0	1	1			
		16/07/91	16/07/91	1	2	1	100.0	100.0	1	0	9e		
						43							
5	Reboxetine	12/06/91	12/06/91	1	2	1	100.0	100.0	0	1	9m		
		13/06/91	01/07/91	19	2	2	100.0	100.0	1	1			
		02/07/91	02/07/91	1	2	1	50.0	97.6	1	1	6e		
						21							
6	Placebo	23/05/91	23/05/91	1	2	1	100.0	100.0	0	1	9m		
		24/05/91	05/07/91	43	2	2	100.0	100.0	1	1			
						44							
						44							
7	Reboxetine	27/08/91	27/08/91	1	2	1	100.0	100.0	0	1	9m		
		28/08/91	05/09/91	9	2	2	100.0	100.0	1	1			
		06/09/91	06/09/91	1	2	1	50.0	95.5	1	1	1e		
						44							

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 m = morning, e = evening

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2

PHARMACIA CNS 888
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 9.0
 EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	Comp. day	Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)	
1	7	Reboxetine	07/09/91	07/10/91	31	2	2	100.0	98.8	1	1	9e		
			08/10/91	08/10/91	1	2	1	100.0	98.8	1	0			
8	B	Placebo	43			14	2	2	100.0	100.0	1	1	10e	
			15/09/91	20/09/91	2	2	1	50.0	93.8	1	1			
			21/09/91	24/09/91	4	2	2	100.0	95.0	1	1			
			25/09/91	25/09/91	1	2	1	50.0	92.9	1	1			
			26/09/91	27/09/91	2	2	1	50.0	89.1	1	1			
			28/09/91	18/10/91	21	2	2	100.0	94.3	1	1			
			19/10/91	19/10/91	1	2	1	100.0	94.4	1	0			
			45			1	2	1	100.0	100.0	0	1		
9	Reboxetine	27/11/91	27/11/91	1	2	2	100.0	100.0	1	1	9e			
		28/11/91	05/01/92	39	2	2	100.0	100.0	1	0				
		06/01/92	06/01/92	1	2	1	100.0	100.0	1	0				
		41			1	2	1	100.0	100.0	0	1	9m		
10	Placebo	24/09/91	24/09/91	1	2	2	100.0	100.0	0	1	9m			
		25/09/91	13/10/91	19	2	2	100.0	100.0	1	1	10e			
		14/10/91	14/10/91	1	2	1	50.0	97.6	1	1				
		15/10/91	03/11/91	20	2	2	100.0	98.8	1	1				
		04/11/91	04/11/91	1	2	1	100.0	98.8	1	0	9e			
		42			4	2	2	100.0	100.0	1	1			
11	Imipramine	10/10/91	13/10/91	4	2	2	100.0	100.0	1	1				
12	Imipramine	18/10/91	29/11/91	43	2	2	100.0	100.0	1	1				
		30/11/91	30/11/91	1	2	1	100.0	100.0	1	0	9e			
412	Reboxetine	44			1	2	1	100.0	100.0	0	1	9m		
		13/11/91	13/11/91	1	2	2	100.0	100.0	1	1	6e			
		14/11/91	22/12/91	39	2	2	100.0	100.0	1	1				
		23/12/91	23/12/91	1	2	1	50.0	98.8	1	1				

1025

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

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3

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)								
1	413	Placebo	09/12/91 20/01/92	19/01/92 28/01/92	42 1	2 2	2 1	100.0 100.0	100.0 100.0	1 1	1 0	9e									
														43							
														8	2	2	100.0	100.0	1	1	
														8							
415	Imipramine	Imipramine	14/01/92 15/01/92 28/01/92 29/01/92 06/02/92 07/02/92	14/01/92 27/01/92 28/01/92 05/02/92 06/02/92 27/02/92	1 13 8 1 21	2 2 2 2 2 2	1 2 1 2 2 2	100.0 100.0 50.0 100.0 0.0 100.0	100.0 100.0 96.7 97.3 93.3 96.7	0 1 1 1 1 1	1 1 1 1 1 1	9m 10e 10m 10e									
														45							
														1	2	1	100.0	100.0	0	1	9m
														6	2	2	100.0	100.0	1	1	
														1	2	3	0.0	87.5	2	1	9e
														4	2	2	100.0	91.7	1	1	yes
421	Imipramine	Imipramine	27/02/92 28/02/92	27/02/92 09/04/92	1 42	2 2	1 2	100.0 100.0	100.0 100.0	0 1	1 1	9m									
														12							
422	Imipramine	Imipramine	05/08/92 15/08/92 16/08/92 20/08/92 21/08/92 26/08/92 27/08/92 28/08/92 02/09/92 03/09/92	14/08/92 15/08/92 19/08/92 20/08/92 25/08/92 26/08/92 27/08/92 01/09/92 02/09/92 09/09/92	10 1 4 1 5 1 5 5 1 7	2 2 2 2 2 2 2 2 2 2	2 1 2 1 2 2 2 2 2 2	100.0 50.0 100.0 50.0 100.0 50.0 100.0 0.0 100.0 100.0	100.0 95.5 96.7 93.8 95.2 93.2 91.3 92.9 89.7 91.7	1 1 1 1 1 1 1 1 1 1	1 1 1 1 1 1 1 1 1 1	1e 1e 1e 1e 1m 10m 10e									
														43							
														10	2	2	100.0	100.0	1	1	
														4	2	2	100.0	96.7	1	1	1e
														1	2	1	50.0	93.8	1	1	1e
														5	2	2	100.0	95.2	1	1	1e
														1	2	1	50.0	93.2	1	1	1e
														5	2	2	100.0	91.3	1	1	1m
														1	2	2	0.0	92.9	1	1	1m
														7	2	2	100.0	89.7	1	1	10m 10e

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration, 8=morning, e=evening

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	Z	X	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
								day	cumulat.				
1	422	Imipramine	10/09/92	10/09/92	1	2	2	0.0	89.2			1m 1e	
			11/09/92	17/09/92	7	2	2	100.0	90.9	1	1		
					44								
2/1	49	Placebo	18/05/91	28/06/91	42	2	2	100.0	100.0	1	1		
					42								
50	Reboxetine	27/12/91	05/02/92	41	2	2	100.0	100.0	1	1		6e	
		06/02/92	06/02/92	1	2	1	50.0	98.8	1				
					42								
51	Imipramine	02/02/92	15/03/92	43	2	2	100.0	100.0	1	1			
				43									
2/2	43	Imipramine	18/04/91	18/04/91	1	2	1	100.0	100.0	0	1	9m	
			19/04/91	23/04/91	5	2	2	100.0	100.0	1	1		
			24/04/91	24/04/91	1	2	1	100.0	100.0	1		3e	
			25/04/91	02/05/91	8	2	2	100.0	100.0	1	1	3m 3e	
			03/05/91	16/05/91	14	2	2	100.0	100.0	1	1		
					29								
44	Imipramine	19/07/91	19/07/91	1	2	0	50.0	50.0	0	0	9m 1e		
		20/07/91	29/08/91	41	2	2	100.0	98.8	1	1			
					42								
45	Reboxetine	08/09/91	20/10/91	43	2	2	100.0	100.0	1	1			
				43									
46	Placebo	26/09/91	26/09/91	1	2	1	100.0	100.0	0	1	9m		
		27/09/91	10/10/91	14	2	2	100.0	100.0	1	1			
		11/10/91	16/10/91	6	2	1	100.0	100.0	1	1	3m 3e		
		17/10/91	17/10/91	1	2	1	100.0	100.0	1	1	3m		
		18/10/91	22/10/91	5	2	2	100.0	100.0	1	1			
		23/10/91	23/10/91	1	2	1	100.0	100.0	1	0	9e		

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration, 8=double low dose, 9=evening

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5

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PHARMACIA CNS R8D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
2/2	47	Placebo	24/03/92	05/04/92	28	2	2	100.0	100.0	1	1		
					13	2	1	50.0	96.4	1		1e	
					1	2	2	100.0	98.8	1			
					26	2	1	50.0	97.6	1		1m	
					1	2	2	100.0	97.6	1			
			04/05/92	04/05/92	1	2	2	100.0	97.6	1			
					42								
48	Reboxetine		07/04/92	04/05/92	28	2	2	100.0	100.0	1	1		
					1	2	2	100.0	96.6	1		1m 1e	
					1	2	2	100.0	97.7	1			
					44	2	2	100.0	97.7	1			
					43								
2/3	36/A	Imipramine	07/03/91	17/04/91	42	2	2	100.0	100.0	1	1		
					42								
37	Reboxetine		27/03/91	07/05/91	42	2	2	100.0	100.0	1	1		
					42								
38	Placebo		14/08/91	25/09/91	43	2	2	100.0	100.0	1	1		
					43								
39	Imipramine		10/08/91	20/09/91	42	2	2	100.0	100.0	1	1		
					42								
40	Reboxetine		24/10/91	04/12/91	42	2	2	100.0	100.0	1	1		
					42								
41	Placebo		03/10/91	13/11/91	42	2	2	100.0	100.0	1	1		
					42								
42	Imipramine		19/05/92	30/06/92	43	2	2	100.0	100.0	1	1		
					42								

1028

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

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6

PHARMACIA CNS 8&D

REBOXETINE - PROTOCOL 2012A/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z Cumpl. day	Z Cumpl. cumulat.	Morning Cps	Afternoon Cps	Reason (z)	Overdose (xx)		
2/4	31	Placebo	26/03/91	05/05/91	43	2	2	100.0	100.0	1	1				
					41	2	2	100.0	100.0	1	1				
					41	2	2	100.0	100.0	1	1				
32	Reboxetine	26/10/91	06/12/91	42	2	2	100.0	100.0	100.0	1	1				
				42	2	2	100.0	100.0	100.0	100.0	1	1			
				42	2	2	100.0	100.0	100.0	100.0	1	1			
33	Imipramine	29/05/91	29/05/91	1	2	1	100.0	100.0	100.0	0	1	9m			
				41	2	2	100.0	100.0	100.0	100.0	1	1			
				41	2	1	100.0	100.0	100.0	100.0	1	0	9e		
34	Placebo	17/04/92	28/05/92	43	2	2	100.0	100.0	100.0	1	1				
				42	2	2	100.0	100.0	100.0	100.0	1	1			
				42	2	2	100.0	100.0	100.0	100.0	1	1			
35	Reboxetine	15/09/92	26/10/92	42	2	2	100.0	100.0	100.0	1	1				
				42	2	2	100.0	100.0	100.0	100.0	1	1			
				42	2	2	100.0	100.0	100.0	100.0	1	1			
36	Imipramine	12/02/92	24/03/92	42	2	2	100.0	100.0	100.0	1	1				
				42	2	2	100.0	100.0	100.0	100.0	1	1			
				42	2	2	100.0	100.0	100.0	100.0	1	1			
2/5	73	Placebo	07/02/92	20/03/92	43	2	2	100.0	100.0	1	1				
					43	2	2	100.0	100.0	100.0	100.0	1	1		
					43	2	2	100.0	100.0	100.0	100.0	1	1		
74	Reboxetine	21/06/92	01/08/92	42	2	2	100.0	100.0	100.0	1	1				
				42	2	2	100.0	100.0	100.0	100.0	1	1			
				42	2	2	100.0	100.0	100.0	100.0	1	1			
75	Imipramine	11/09/92	22/10/92	42	2	2	100.0	100.0	100.0	1	1				
				42	2	2	100.0	100.0	100.0	100.0	1	1			
				42	2	2	100.0	100.0	100.0	100.0	1	1			
76	Imipramine	15/09/92	26/10/92	42	2	2	100.0	100.0	100.0	1	1				
				42	2	2	100.0	100.0	100.0	100.0	1	1			
				42	2	2	100.0	100.0	100.0	100.0	1	1			

1029

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 m = morning, e = evening

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7

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 9.0
 EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z Cumpl. day	X Cumpl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
2/5	77	Placebo	22/05/92	02/11/92	42	2	2	100.0	100.0	1	1		
					42								
2/6	55	Reboxetine	12/06/92	02/07/92	35	2	2	100.0	100.0	1	1		
					35								
2/6	56	Reboxetine	12/06/92	02/07/92	21	2	2	100.0	100.0	1	1		(3 - m) (3 - e)
					21	2	4	100.0	100.0	2	2		
1030	57	Imipramine	03/07/92	23/07/92	42	2	2	100.0	100.0	1	1		(3 - m) (3 - e)
					21	2	4	100.0	100.0	2	2		
58	58	Placebo	05/05/92	26/05/92	21	2	2	100.0	100.0	1	1		(3 - m) (3 - e)
					21	2	4	100.0	100.0	2	2		
59	59	Placebo	18/05/92	09/06/92	22	2	2	100.0	100.0	1	1		(3 - m) (3 - e)
					21	2	4	100.0	100.0	2	2		
3/1	61	Imipramine	27/05/92	17/06/92	43	2	2	100.0	100.0	1	1		(3 - m) (3 - e)
					28	2	4	100.0	100.0	2	2		
3/1	60	Imipramine	12/05/92	02/06/92	21	2	2	100.0	100.0	1	1		(3 - m) (3 - e)
					21	2	4	100.0	100.0	2	2		
3/1	61	Imipramine	05/03/91	21/03/91	42	2	2	100.0	100.0	1	1		(3 - m) (3 - e)
					16	2	1	50.0	97.1	1	1	1m	

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 8=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 m = morning, e = evening

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	X cumulat.	Compl. Morning Cps	Afternoon Cps	Reason (%)	Overdose (**)	
3/1	61	Imipramine	22/03/91	22/03/91	1	2	2	100.0	97.2	1	1			
			23/03/91	23/03/91	1	2	1	50.0	94.7	1	1	1a		
			24/03/91	31/03/91	8	2	2	100.0	96.3	-	1	1	1a	
			01/04/91	01/04/91	1	2	1	50.0	94.6		1	1	1a	
			02/04/91	07/04/91	6	2	2	100.0	95.6	1	1			
			08/04/91	08/04/91	1	2	1	50.0	94.3	1	1	1a		
					35									
			16/04/91	26/05/91	41	2	2	100.0	100.0	1	1	1		
63	Placebo	13/05/91	23/06/91	42	2	2	100.0	100.0	1	1				
				42										
64	Placebo	14/03/91	01/04/91	19	2	2	100.0	100.0	1	1				
		02/04/91	02/04/91	1	2	1	50.0	97.5	1	1	1a			
		03/04/91	24/04/91	22	2	2	100.0	96.8	1	1				
65	Reboxetine	16/09/91	27/10/91	42	2	2	100.0	100.0	1	1				
				42										
66	Reboxetine	10/06/91	21/07/91	42	2	2	100.0	100.0	1	1				
				42										
139	Imipramine	03/09/91	12/09/91	10	2	2	100.0	100.0	1	1				
				10										
140	Placebo	12/09/91	23/10/91	42	2	2	100.0	100.0	1	1				
				42										
141	Placebo	03/10/91	14/11/91	43	2	2	100.0	100.0	1	1				
				43										

1031

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

9550082

9

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)		
3/1	142	Imipramine	18/11/91	08/12/91	21	2	2	100.0	100.0	1	1				
					21										
143	Reboxetine	15/04/92	15/04/92	15/04/92	1	2	1	100.0	100.0	0	1	9m			
					34	2	2	100.0	100.0	1	1				
					20/05/92	20/05/92	1	2	1	50.0	98.6	1		6e	
144	Reboxetine	09/06/92	09/06/92	09/06/92	1	2	1	100.0	100.0	0	1	9m			
					43	2	2	100.0	100.0	1	1				
451	Reboxetine	20/01/92	20/01/92	20/01/92	1	2	1	100.0	100.0	0	1	9m			
					11	2	2	100.0	100.0	1	1				
					01/02/92	01/02/92	1	2	1	50.0	96.2	1		6e	
					13										
452	Placebo	22/01/92	22/01/92	22/01/92	1	2	1	100.0	100.0	0	1	9m			
					41	2	2	100.0	100.0	1	1				
					04/03/92	04/03/92	1	2	1	100.0	100.0	1		9e	
453	Imipramine	29/01/92	29/01/92	29/01/92	1	2	1	100.0	100.0	0	1	9m			
					41	2	2	100.0	100.0	1	1				
454	Reboxetine	17/02/92	17/02/92	17/02/92	1	2	1	100.0	100.0	0	1	9m			
					43	2	2	100.0	100.0	1	1				
					01/04/92	01/04/92	1	2	1	100.0	100.0	1		9e	
455	Placebo	11/03/92	11/03/92	11/03/92	1	2	1	100.0	100.0	0	1	9m			
					43	2	2	100.0	100.0	1	1				

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(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

10

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	% Compl. day	% Cumulat.	Morning Cps	Afternoon Cps	Reason (%)	Overdose (**)
3/1	456	Imipramine	25/03/92	25/03/92	1	2	1	100.0	100.0	0	1	9m	
			26/03/92	02/04/92	8	2	2	100.0	100.0	1	1		
			03/04/92	03/04/92	1	2	1	100.0	100.0	1	1	3e	
					10								
3/2	65/A	Reboxetine	29/01/91	25/02/91	28	2	2	100.0	100.0	1	1		
			26/02/91	27/02/91	2	2	4	100.0	100.0	2	2		
			28/02/91	11/03/91	12	2	2	100.0	100.0	1	1		
					42								
3/3	67	Placebo	18/07/91	28/08/91	42	2	2	100.0	100.0	1	1		
					42								
3/4	68	Reboxetine	21/01/92	02/03/92	42	2	2	100.0	100.0	1	1		
					42								
3/5	69	Placebo	04/02/92	16/03/92	42	2	2	100.0	100.0	1	1		
					42								
3/6	70	Imipramine	15/04/92	26/05/92	42	2	2	100.0	100.0	1	1		
					42								
3/7	71	Imipramine	16/04/92	27/05/92	42	2	2	100.0	100.0	1	1		
					42								
3/8	72	Reboxetine	25/07/92	04/09/92	42	2	2	100.0	100.0	1	1		
					42								
3/9	79	Imipramine	04/05/91	05/05/91	2	2	2	100.0	100.0	1	1		
			06/05/91	06/05/91	1	2	3	50.0	83.3	2	2		
			07/05/91	07/05/91	1	2	4	0.0	62.5	2	2		
			08/05/91	03/06/91	27	2	2	100.0	95.2	1	1		
			04/06/91	04/06/91	1	2	1	50.0	53.8	1	1		10n
			05/06/91	15/06/91	11	2	2	100.0	95.3	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration, 8=high daily dose in one administration, 9=low daily dose in one administration, 10n = morning, e = evening

9550082

11

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cmpl. Cps	Z Cumpl. day	Z Cumpl. cumulat. Cps	Morning Cps	Afternoon Cps	Reason (x)	Overdose (xx)
3/4	80	Imipramine	01/09/91	24/09/91	43	2	2	100.0	100.0	1	1		
					24	2	2	100.0	100.0	1	1		
					24	2	2	100.0	100.0	1	1		
81	Reboxetine	17/05/91	27/06/91	42	2	2	100.0	100.0	100.0	1	1		
				42	2	2	100.0	100.0	100.0	1	1		
				42	2	2	100.0	100.0	100.0	1	1		
82	Placebo	17/06/91	28/07/91	42	2	2	100.0	100.0	100.0	1	1		
				42	2	2	100.0	100.0	100.0	1	1		
				42	2	2	100.0	100.0	100.0	1	1		
83	Placebo	17/06/91	17/06/91	1	2	1	100.0	100.0	100.0	0	1	9m	
				6	2	2	100.0	100.0	100.0	1	1		
				6	2	2	100.0	100.0	100.0	1	1		
				1	2	1	50.0	93.8	1	1	6e		
84	Reboxetine	09/10/91	22/11/91	45	2	2	100.0	100.0	100.0	1	1	9e	
				45	2	1	100.0	100.0	100.0	1	0		
				46	2	2	100.0	100.0	100.0	1	1		
85	Imipramine	29/10/91	08/12/91	41	2	2	100.0	100.0	100.0	1	1		
				41	2	2	100.0	100.0	100.0	1	1		
86	Imipramine	03/12/91	14/01/92	43	2	2	100.0	100.0	100.0	1	1	9e	
				43	2	1	100.0	100.0	100.0	1	0		
				44	2	2	100.0	100.0	100.0	1	1		
87	Placebo	09/12/91	19/01/92	42	2	2	100.0	100.0	100.0	1	1		
				42	2	2	100.0	100.0	100.0	1	1		
88	Placebo	23/03/92	23/03/92	1	2	1	100.0	100.0	100.0	0	1	9m	
				4	2	2	100.0	100.0	100.0	1	1		
				1	2	4	0.0	83.3	2	2			
				1	2	3	50.0	78.6	1	2			
				42	2	2	100.0	100.0	100.0	1	1		

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

1034

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12

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	Z	Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)		
3/4	88	Placebo	30/03/92	30/03/92	1	2	9	75.0	78.1	2	1					
			31/03/92	19/04/92	20	2	2	100.0	93.8	1	1					
			20/04/92	21/04/92	2	2	1	50.0	90.8	1		4e				
			22/04/92	22/04/92	1	2	1	50.0	89.5	1	1	4m				
			23/04/92	07/05/92	15	2	2	100.0	92.9	1	1					
			08/05/92	08/05/92	1	2	1	100.0	93.1	1	0	9e				
					47											
					41	26/03/92	05/05/92	2	2	100.0	100.0	1	1			
					1	06/05/92	06/05/92	1	2	100.0	100.0	1	0	9e		
					42											
89	Reboxetine															
90	Reboxetine															
457	Placebo															
458	Reboxetine															
459	Placebo															
460	Reboxetine															
461	Imipramine															

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration, 8=m = morning, e = evening

1035

9550082

13

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	% compliat.	Morning Cps	Afternoon Cps	Reason (%)	Overdose (xx)
1/4	462	Imipramine	29/09/92	29/09/92	1	2	1	100.0	100.0	0	1	9m	
			30/09/92	07/10/92	8	2	2	100.0	100.0	1	1		
			08/10/92	08/10/92	1	2	1	50.0	95.0	1			6e
					10								
1/1	91	Imipramine	12/10/91	22/11/91	42	2	2	100.0	100.0	1	1		
					42								
92		Reboxetine	07/08/91	17/09/91	42	2	2	100.0	100.0	1	1		
					42								
93		Placebo	03/07/91	15/08/91	44	2	2	100.0	100.0	1	1		
			16/08/91	16/08/91	1	2	1	100.0	100.0	1	0		9b
					45								
94		Placebo	05/07/91	19/07/91	15	2	2	100.0	100.0	1	1		
			20/07/91	23/07/91	4	2	1	50.0	89.5	1			4e
			24/07/91	13/08/91	21	2	2	100.0	95.0	1	1		
					40								
95		Imipramine	03/06/91	16/07/91	44	2	2	100.0	100.0	1	1		
					44								
96		Reboxetine	04/09/91	16/10/91	43	2	2	100.0	100.0	1	1		
					43								
115		Reboxetine	06/05/92	16/06/92	42	2	2	100.0	100.0	1	1		
					42								
116		Imipramine	16/05/92	21/05/92	6	2	2	100.0	100.0	1	1		
			22/05/92	22/05/92	1	2	1	50.0	92.9	1			6e

1036

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/ond treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

14

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	X	Z	Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
4/1	117	Imipramine	03/09/91	14/10/91	42	2	2	100.0	100.0	1	1	1	1		
					42										
118		Reboxetine	23/05/92	03/07/92	42	2	2	100.0	100.0	1	1	1	1		
					42										
120		Placebo	31/07/92	31/07/92	1	2	1	100.0	100.0	0	1	1	1	9m	
			01/08/92	11/09/92	42	2	2	100.0	100.0	1	1	1	1		
					43										
145		Imipramine	30/09/92	05/10/92	6	2	2	100.0	100.0	1	1	1	1		
			06/10/92	06/10/92	1	2	1	50.0	92.9	1	1	1	1	10m	
			07/10/92	10/11/92	35	2	2	100.0	98.8	1	1	1	1		
					42										
146		Placebo	16/09/92	26/10/92	41	2	2	100.0	100.0	1	1	1	1		
			27/10/92	27/10/92	1	2	1	100.0	100.0	1	0	1	0	9e	
					42										
147		Reboxetine	01/09/92	02/09/92	2	2	2	100.0	100.0	1	1	1	1		
			03/09/92	03/09/92	1	2	1	50.0	83.3	1	1	1	1	10e	
			04/09/92	12/10/92	39	2	2	100.0	98.8	1	1	1	1		
					42										
148		Imipramine	26/09/92	06/11/92	42	2	2	100.0	100.0	1	1	1	1		
					42										
149		Reboxetine	30/09/92	10/11/92	42	2	2	100.0	100.0	1	1	1	1		
					42										
150		Placebo	30/09/92	10/11/92	42	2	2	100.0	100.0	1	1	1	1		

1037

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

15

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	Z Cumul. compl.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (xx)
4/2	93/A	Placebo	22/02/91	04/04/91	42	2	2	100.0	100.0	1	1		
					42								
4/3	99/A	Placebo	27/03/91	07/05/91	42	2	2	100.0	100.0	1	1		
					42								
104		Reboxetine	22/05/91	02/07/91	42	2	2	100.0	100.0	1	1		
					42								
4/3	97	Placebo	17/04/91	29/04/91	13	2	2	100.0	100.0	1	1		
			30/04/91	30/04/91	1	2	1	50.0	96.4	1		10e	
			01/05/91	28/05/91	28	2	2	100.0	98.8	1	1		
					42								
103	98	Reboxetine	20/06/91	11/07/91	22	2	2	100.0	100.0	1	1		
			12/07/91	12/07/91	1	2	1	50.0	97.8	1		1e	
			13/07/91	21/07/91	9	2	2	100.0	98.4	1	1		
					32								
103	99	Placebo	08/08/91	14/08/91	7	2	2	100.0	100.0	1	1		
			15/08/91	15/08/91	1	2	1	50.0	93.8	1		6e	
					8								
100		Imipramine	27/11/91	27/11/91	1	2	1	100.0	100.0	0	1		9m
			28/11/91	17/12/91	20	2	2	100.0	100.0	1	1		
					21								
101		Imipramine	17/03/92	27/04/92	42	2	2	100.0	100.0	1	1		
					42								
4/4	109	Reboxetine	05/06/91	19/07/91	42	2	2	100.0	100.0	1	1		

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 8=start/stop treatment in morning or evening, 9=reason unknown
(xx) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

16

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z Cumpl. day	Z Cumpl. cumulat.	Morning Cps	Afternoon Cps	Reason (x)	Overdose (xx)
4/4	110	Imipramine	15/06/91	26/07/91	42	2	2	100.0	100.0	1	1		
					42								
	111	Imipramine	04/07/91	14/08/91	42	2	2	100.0	100.0	1	1		
					42								
	112	Placebo	10/07/91	20/08/91	42	2	2	100.0	100.0	1	1		
					42								
	113	Reboxetine	31/08/91	11/10/91	42	2	2	100.0	100.0	1	1		
					42								
	114	Placebo	20/11/91	31/12/91	42	2	2	100.0	100.0	1	1		
					42								
	175	Imipramine	13/02/92	25/03/92	42	2	2	100.0	100.0	1	1		
					42								
	176	Placebo	14/03/92	07/04/92	25	2	2	100.0	100.0	1	1		
			08/04/92	08/04/92	1	2	1	50.0	98.1	1		6e	
					26								
	177	Imipramine	28/04/92	11/05/92	14	2	2	100.0	100.0	1	1		
					14								
	178	Reboxetine	28/04/92	08/06/92	42	2	2	100.0	100.0	1	1		
					42								
	179	Placebo	11/09/92	28/09/92	18	2	2	100.0	100.0	1	1		
			29/09/92	29/09/92	1	2	1	50.0	97.4	1		6e	

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

17

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	% Compl. day	Cumul. compl. Cps	% Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (%)	Overdose (xx)
					19									
4/4	180	Reboxetine	07/10/92	17/11/92	42	2	2	100.0	100.0	100.0	1	1		
					42									
5/1	127	Reboxetine	06/06/91	17/07/91	42	2	2	100.0	100.0	100.0	1	1		
					42									
128		Reboxetine	14/06/91	25/07/91	42	2	2	100.0	100.0	100.0	1	1		
					42									
129		Placebo	24/12/91	03/02/92	42	2	2	100.0	100.0	100.0	1	1		
					42									
130		Placebo	05/03/92	14/04/92	41	2	2	100.0	100.0	100.0	1	1	5e	
			15/04/92	15/04/92	1	2	1	100.0	100.0	100.0	1			
					42									
131		Imipramine	21/03/92	30/04/92	41	2	2	100.0	100.0	100.0	1	1		
					41									
132		Imipramine	25/06/92	06/08/92	43	2	2	100.0	100.0	100.0	1	1		
					43									
5/2	121	Imipramine	20/12/91	26/01/92	38	2	2	100.0	100.0	100.0	1	1		
			27/01/92	27/01/92	1	2	1	50.0	98.7	98.7	1		6e	
					39									
125		Reboxetine	28/01/91	23/02/91	27	2	2	100.0	100.0	100.0	1	1		
			24/02/91	24/02/91	1	2	1	50.0	98.2	98.2	1		1e	
			25/02/91	09/03/91	13	2	2	100.0	98.8	98.8	1	1		
			10/03/91	10/03/91	1	2	1	50.0	97.6	97.6	1		1e	

1040

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 8=start/end treatment in morning or evening, 9=reason unknown
 (xx) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 m = morning, e = evening

9550082

18

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	Z Cumul. compl. day	X Cumul. compl. Cps	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)	
5/3	133	Placebo	29/11/91	12/12/91	42	2	2	100.0	100.0	1	1			
					14									
					14									
134	Reboxetine	06/12/91	16/01/92	42	2	2	100.0	100.0	1	1				
				42										
135	Imipramine	10/01/92	20/02/92	42	2	2	100.0	100.0	1	1				
				42										
136	Imipramine	02/03/92	07/03/92	6	2	2	100.0	100.0	1	1				
				1	2	1	50.0	92.9	1					
				35	2	2	100.0	96.8	1		10e			
				42										
137	Reboxetine	15/05/92	25/06/92	42	2	2	100.0	100.0	1	1				
				42										
138	Placebo	15/05/92	15/05/92	1	2	2	100.0	100.0	1	1				
				1	2	1	50.0	75.0	1			6e		
				2										
6/1	151	Imipramine	21/01/92	21/01/92	1	2	1	100.0	100.0	0	1		9m	
					6	2	2	100.0	100.0	1	1			
					1	2	1	50.0	93.8	1			6e	
152	Reboxetine	24/02/92	07/04/92	44	2	2	100.0	100.0	1	1				
				44										
153	Reboxetine	18/03/91	18/03/91	1	2	1	100.0	100.0	0	1		9m		
				41	2	2	100.0	100.0	1	1				
				1	2	1	100.0	100.0	1	0		9e		

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 n = morning, e = evening

9550082

19

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 9.0
 EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	Z	Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (xx)
6/1	154	Imipramine	30/03/92	06/04/92	43	2	0.0	0.0						
					8	2	100.0	100.0	1	1				
					8	2	100.0	100.0	1	1				
6/2	155	Placebo	08/07/92	04/08/92	28	2	100.0	100.0						
					28	2	100.0	100.0	1	1				
					42	2	100.0	100.0	1	1				
6/2	156	Placebo	08/09/92	19/10/92	42	2	100.0	100.0						
					42	2	100.0	100.0	1	1				
					42	2	100.0	100.0	1	1				
6/2	157	Reboxetine	30/04/91	26/05/91	27	2	100.0	100.0						
					1	2	50.0	58.2	1	1	1e			
					14	2	100.0	98.8	1	1				
6/2	158	Imipramine	24/11/91	05/01/92	42	2	100.0	100.0						
					43	2	100.0	100.0	1	1				
					43	2	100.0	100.0	1	1				
6/2	159	Imipramine	14/07/91	24/08/91	42	2	100.0	100.0						
					42	2	100.0	100.0	1	1				
					42	2	100.0	100.0	1	1				
6/2	160	Placebo	24/11/91	04/01/92	42	2	100.0	100.0						
					42	2	100.0	100.0	1	1				
					42	2	100.0	100.0	1	1				
6/2	161	Reboxetine	20/02/92	18/03/92	23	2	100.0	100.0						
					28	2	100.0	100.0	1	1				
					28	2	100.0	100.0	1	1				
6/2	162	Placebo	10/07/91	12/07/91	3	2	100.0	100.0						
					1	2	50.0	87.5	1	1	6e			
					4	2	100.0	100.0	1	1				
6/2	169	Imipramine	26/12/91	15/01/92	21	2	100.0	100.0						
					21	2	100.0	100.0	1	1				
					21	2	100.0	100.0	1	1				

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 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

1042

9550082

20

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	X cumulat.	Morning Cps	Afternoon Cps	Reason (%)	Overdose (**)
6/2	170	Placebo	01/11/91	15/11/91	21	2	2	100.0	100.0	1	1		
					15	2	2	100.0	100.0	1	1		
					15	2	2	100.0	100.0	1	1		
171	Imipramine	22/07/92	01/09/92	42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
172	Reboxetine	07/07/92	17/08/92	42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
173	Placebo	05/07/92	15/08/92	42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
174	Reboxetine	11/05/92	21/06/92	42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
6/3	163	Reboxetine	06/06/91	07/06/91	2	2	2	100.0	100.0	1	1		
					1	2	1	50.0	83.3	1	1	6e	
					3	2	2	100.0	100.0	1	1		
164	Imipramine	11/10/91	21/11/91	42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
				42	2	2	100.0	100.0	1	1			
165	Imipramine	16/10/91	25/11/91	41	2	2	100.0	100.0	1	1			
				1	2	1	100.0	100.0	1	1	5e		
				42	2	2	100.0	100.0	1	1			
166	Reboxetine	25/10/91	29/10/91	5	2	2	100.0	100.0	1	1			
				5	2	2	100.0	100.0	1	1			
				5	2	2	100.0	100.0	1	1			
167	Placebo	18/11/91	18/11/91	1	2	1	100.0	100.0	0	1		9m	
				20	2	2	100.0	100.0	1	1			
				20	2	2	100.0	100.0	1	1			

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 8=start/end treatment in morning or evening, 9=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
n = morning, e = evening

9550082

21

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	% Compl.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
6/3	167	Placebo	09/12/91	09/12/91	1	2	1	50.0	97.7	1	1	10e	
			10/12/91	27/12/91	18	2	2	100.0	98.8	1	1		
					40								
	168	Placebo	03/12/91	05/01/92	34	2	2	100.0	100.0	1	1	9e	
			06/01/92	06/01/92	1	2	1	100.0	100.0	1	0		
					35								
	505	Imipramine	03/12/91	17/12/91	15	2	2	100.0	100.0	1	1		
					15								
	506	Placebo	08/01/92	08/01/92	1	2	1	100.0	100.0	0	1	9m	
			09/01/92	19/02/92	42	2	2	100.0	100.0	1	1		
					43								
	507	Imipramine	14/01/92	24/02/92	42	2	2	100.0	100.0	1	1		
					42								
	508	Reboxetine	05/02/92	17/03/92	42	2	2	100.0	100.0	1	1		
					42								
	509	Placebo	24/02/92	24/02/92	1	2	1	100.0	100.0	0	1	9m	
			25/02/92	06/04/92	42	2	2	100.0	100.0	1	1		
					43								
	510	Reboxetine	27/02/92	09/03/92	12	2	2	100.0	100.0	1	1	6e	
			10/03/92	10/03/92	1	2	1	50.0	96.2	1	1		
					13								
	511	Imipramine	19/03/92	21/04/92	34	2	2	100.0	100.0	1	1		
					34								
	512	Placebo	01/04/92	01/04/92	1	2	1	100.0	100.0	1	1	3e	
					34								

1044

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(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
m = morning, e = evening

9550082

22

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z Compl. day	Z Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (xx)
					1								
6/3	513	Imipramine	13/05/92	23/06/92	42	2	2	100.0	100.0	1	1		
					42								
7/02	181	Reboxetine	27/01/92	08/03/92	42	2	2	100.0	100.0	1	1		
					42								
	182	Placebo	23/11/91	03/01/92	42	2	2	100.0	100.0	1	1		
					42								
	183	Imipramine	02/01/92	15/01/92	14	2	2	100.0	100.0	1	1		
			16/01/92	18/01/92	3	2	0.0	82.4					
					17								
	184	Imipramine	27/01/92	08/03/92	42	2	2	100.0	100.0	1	1		
					42								
	185	Reboxetine	10/04/92	04/05/92	25	2	2	100.0	100.0	1	1		
			05/05/92	05/05/92	1	2	1	50.0	98.1	1	1	60	
					26								
	186	Placebo	16/04/92	27/05/92	42	2	2	100.0	100.0	1	1		
					42								
	535	Placebo	15/04/92	26/05/92	42	2	2	100.0	100.0	1	1		
					42								
	536	Reboxetine	08/05/92	18/06/92	42	2	2	100.0	100.0	1	1		
					42								
7/03	187	Imipramine	18/02/92	30/03/92	42	2	2	100.0	100.0	1	1		

1045

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 8=start/end treatment in morning or evening, 9=reason unknown
(xx) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
m = morning, e = evening

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

23

PHARMACIA CNS R&D
 REBOXYTINE - PROTOCOL 20124/015
 Listing No.: 9.0
 EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z Cumpl. day	Z Cumpl. cumulat.	Morning Cps	Afternoon Cps	Reason (x)	Overdose (xx)
7/03	188	Placebo	25/02/92	06/04/92	42	2	2	100.0	100.0	1	1		
					42								
	189	Placebo	25/02/92	06/04/92	42	2	2	100.0	100.0	1	1		
					42								
	190	Reboxetine	28/02/92	09/04/92	42	2	2	100.0	100.0	1	1		
					42								
	191	Imipramine	03/03/92	10/04/92	39	2	2	100.0	100.0	1	1		
					39								
	192	Reboxetine	10/03/92	20/04/92	42	2	2	100.0	100.0	1	1		
					42								
	523	Reboxetine	06/05/92	16/06/92	42	2	2	100.0	100.0	1	1		
					42								
	524	Placebo	06/05/92	16/06/92	42	2	2	100.0	100.0	1	1		
					42								
	525	Placebo	06/05/92	16/06/92	42	2	2	100.0	100.0	1	1		
					42								
	526	Reboxetine	06/05/92	16/06/92	42	2	2	100.0	100.0	1	1		
					42								
	527	Imipramine	19/05/92	08/06/92	21	2	2	100.0	100.0	1	1		
					7	2	1	50.0	87.5	1	1		
					14	2	2	100.0	91.7	1	1		
					14	2	2	100.0	91.7	1	1		4a

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 8=low daily dose in one administration
 m = morning, e = evening

1046

9550082

24

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. %	Cumul. compl. %	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
7/03	528	Imipramine	19/05/92 26/05/92	25/05/92 22/06/92	7 28	2 2	6.0 100.0	0.0 80.0	1	1		
					35							
7/04	193	Placebo	25/01/92	06/03/92	42	2	100.0	100.0	1	1		
					42							
194		Reboxetine	25/01/92	06/03/92	42	2	100.0	100.0	1	1		
					42							
195		Placebo	25/01/92	06/03/92	42	2	100.0	100.0	1	1		
					42							
196		Reboxetine	01/02/92 22/02/92 29/02/92 06/03/92 07/03/92	21/02/92 28/02/92 05/03/92 06/03/92 13/03/92	21 7 6 1 7	2 2 2 2 2	100.0 0.0 100.0 50.0 100.0	100.0 75.0 79.4 78.6 82.1	1 2 1 1 1	1 2 1 1 1	4m 10e	(D - e)
					42							
197		Imipramine	01/02/92	13/03/92	42	2	100.0	100.0	1	1		
					42							
198		Imipramine	01/02/92	13/03/92	42	2	100.0	100.0	1	1		
					42							
199		Imipramine	28/03/92 05/05/92 06/05/92	04/05/92 05/05/92 06/05/92	38 1 3	2 2 2	100.0 50.0 100.0	100.0 98.7 98.8	1 1 1	1 1 1	1m	
					42							
200		Placebo	28/03/92	06/05/92	42	2	100.0	100.0	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
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m = morning, e = evening

1047

9550082

25

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	X Cumul. compl. day	X Cumul. compl. Cps	Morning Cps	Afternoon Cps	Reason (%)	Overdose (%)												
7/04	201	Reboxetine	28/03/92	27/04/92	31	2	2	100.0	100.0	1	1	1m 1o													
														28/04/92	28/04/92	1	2	0.0	96.9						
														29/04/92	08/05/92	10	2	100.0	97.6	1	1				
					42																				
202	Reboxetine	04/04/92	27/04/92	24	2	2	100.0	100.0	1	1	1	1e													
														28/04/92	28/04/92	1	2	50.0	98.0						
														29/04/92	15/05/92	17	2	100.0	98.8	1	1				
					42																				
203	Placebo	04/04/92	21/04/92	18	2	2	100.0	100.0	1	1	1	1m													
														22/04/92	22/04/92	1	2	50.0	97.6						
														23/04/92	15/05/92	23	2	100.0	98.6	1	1				
					42																				
204	Imipramine	04/04/92	29/04/92	26	2	2	100.0	100.0	1	1	1	1m													
														30/04/92	30/04/92	1	2	50.0	98.1						
														01/05/92	15/05/92	15	2	100.0	98.8	1	1				
					42																				
7/05	205	Placebo	27/01/92	16/02/92	21	2	100.0	100.0	1	1	1														
														17/02/92	08/03/92	21	2	4	100.0	100.0	2	2			
					42																				
206	Imipramine	28/01/92	09/03/92	42	2	2	100.0	100.0	1	1	1														
					42																				
207	Imipramine	28/01/92	09/03/92	42	2	2	100.0	100.0	1	1	1														
					42																				
208	Reboxetine	30/01/92	11/03/92	42	2	2	100.0	100.0	1	1	1														
					42																				

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, o = evening

1048

(3 - m) (3 - o)

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26

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	Z Compl. day	Z Compl. cumulat. Cps	Morning Cps	Afternoon Cps	Reason (%)	Overdose (xx)
7/05	209	Placebo	05/02/92	17/03/92	42	2	2	100.0	100.0	1	1		
					42								
	210	Reboxetine	07/02/92	19/03/92	42	2	2	100.0	100.0	1	1		
					42								
	541	Reboxetine	17/03/92	27/04/92	42	2	2	100.0	100.0	1	1		
					42								
	542	Imipramine	17/03/92	27/04/92	42	2	2	100.0	100.0	1	1		
					42								
	543	Imipramine	18/03/92	28/04/92	42	2	2	100.0	100.0	1	1		
					42								
	544	Placebo	24/03/92	04/05/92	42	2	2	100.0	100.0	1	1		
					42								
	545	Placebo	25/03/92	05/05/92	42	2	2	100.0	100.0	1	1		
					42								
	546	Reboxetine	25/03/92	05/05/92	42	2	2	100.0	100.0	1	1		
					42								
7/07	529	Placebo	18/02/92	30/03/92	42	2	2	100.0	100.0	1	1		
					42								
	530	Imipramine	20/02/92	04/03/92	14	2	2	100.0	100.0	1	1		
			05/03/92	11/03/92	7	2	0.0	0.0	66.7				

1049

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

9550082

27

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps. prescribed	Daily Cps	Z Compl. day	Z Cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
					21								
7/07	531	Reboxetine	24/02/92	24/03/92	30	2	2	100.0	100.0	1	1		
			25/03/92	25/03/92	1	2	1	50.0	98.4	1	1	1m	
			26/03/92	05/04/92	11	2	2	100.0	98.8	1	1		
					42								
	532	Imipramine	27/04/92	07/06/92	42	2	2	100.0	100.0	1	1		
					42								
	533	Reboxetine	04/05/92	14/06/92	42	2	2	100.0	100.0	1	1		
					42								
	534	Placebo	15/05/92	25/06/92	42	2	2	100.0	100.0	1	1		
					42								
8	211	Reboxetine	13/05/91	26/05/91	14	2	2	100.0	100.0	1	1		
					14								
	212	Placebo	14/09/91	25/10/91	42	2	2	100.0	100.0	1	1		
					42								
	213	Imipramine	22/11/91	24/11/91	3	2	2	100.0	100.0	1	1		
					3								
	214	Reboxetine	23/11/91	03/01/92	42	2	2	100.0	100.0	1	1		
					42								
	215	Placebo	18/02/92	30/03/92	42	2	2	100.0	100.0	1	1		
					42								
	216	Imipramine	27/03/92	07/05/92	42	2	2	100.0	100.0	1	1		

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

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28

PHARMACIA CNS 83D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	Z Cumul. compl. day	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
8	217	Reboxetine	30/03/92	10/05/92	42	2	2	100.0	1	1		
					42							
	218	Reboxetine	09/04/92	20/05/92	42	2	2	100.0	1	1		
					42							
	219	Placebo	11/04/92	01/05/92	21	2	2	100.0	1	1		
					21							
	220	Imipramine	27/04/92	07/06/92	42	2	2	100.0	1	1		
					42							
	221	Imipramine	28/04/92	08/06/92	42	2	2	100.0	1	1		
					42							
	222	Placebo	28/04/92	08/06/92	42	2	2	100.0	1	1		
					42							
	223	Imipramine	11/05/92	21/06/92	42	2	2	100.0	1	1		
					42							
	224	Placebo	07/09/92	18/10/92	42	2	2	100.0	1	1		
					42							
	225	Placebo	11/09/92	22/10/92	42	2	2	100.0	1	1		
					42							
	226	Reboxetine	23/09/92	03/11/92	42	2	2	100.0	1	1		
					42							

1051

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

9550082

29

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2024/015
 Listing No.: 9.0
 EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	% Cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (xx)
8	227	Reboxetine	25/09/92	05/11/92	42	2	2	100.0	100.0	1	1		
					42								
	228	Imipramine	26/09/92	02/10/92	7	2	2	100.0	100.0	1	1		
					7								
	229	Imipramine	30/09/92	10/11/92	42	2	2	100.0	100.0	1	1		
					42								
	230	Reboxetine	28/09/92	08/11/92	42	2	2	100.0	100.0	1	1		
					42								
	231	Imipramine	30/09/92	10/11/92	42	2	2	100.0	100.0	1	1		
					42								
	232	Reboxetine	02/10/92	12/11/92	42	2	2	100.0	100.0	1	1		
					42								
	233	Placebo	07/10/92	17/11/92	42	2	2	100.0	100.0	1	1		
					42								
	234	Placebo	07/10/92	17/11/92	42	2	2	100.0	100.0	1	1		
					42								
8/A	235	Placebo	14/10/92	24/11/92	42	2	2	100.0	100.0	1	1		
					42								
	236	Placebo	14/10/92	24/11/92	42	2	2	100.0	100.0	1	1		
					42								
	237	Reboxetine	14/10/92	24/11/92	42	2	2	100.0	100.0	1	1		

1052

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 8=low daily dose in one administration
 n = morning, e = evening

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30

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0
EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cpl. day	Z Cpl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
8/A	238	Reboxetine	14/10/92	24/11/92	42	2	2	100.0	1	1		
					42							
					42							
239	Imipramine	16/10/92	26/11/92	42	2	2	100.0	1	1			
				42								
				42								
240	Imipramine	16/10/92	26/11/92	42	2	2	100.0	1	1			
				42								
				42								
553	Placebo	16/10/92	26/11/92	42	2	2	100.0	1	1			
				42								
				42								
554	Reboxetine	16/10/92	26/11/92	42	2	2	100.0	1	1			
				42								
				42								
555	Reboxetine	16/10/92	26/11/92	42	2	2	100.0	1	1			
				42								
				42								
556	Imipramine	16/10/92	26/11/92	42	2	2	100.0	1	1			
				42								
				42								
9	241	Placebo	07/02/91	17/02/91	11	2	2	100.0	1	1		
					11							
					11							
242	Reboxetine	18/02/91	10/03/91	21	2	2	100.0	1	1			
					2	1	50.0	97.7	1	1	6e	
					2							
243	Reboxetine	20/02/91	01/03/91	10	2	2	100.0	1	1			
					2	2	50.0	91.7	2	1		
					2	2	100.0	92.9	1	1		(B - m)

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
m = morning, e = evening

1053

9550082

31

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Compl. day	Cumulative compl.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
9	243	Reboxetine	06/03/91	06/03/91	1	2	1	50.0	90.0	1	1	6e	
					15								
	244	Imipramine	19/02/91	12/03/91	22	2	2	100.0	100.0	1	1	6e	
			13/03/91	13/03/91	1	2	1	50.0	97.8	1			
					23								
	245	Imipramine	22/02/91	04/04/91	42	2	2	100.0	100.0	1	1		
					42								
	246	Placabo	22/02/91	17/03/91	24	2	2	100.0	100.0	1	1		
					24								
	247	Placabo	25/02/91	25/03/91	29	2	2	100.0	100.0	1	1	6e	
			26/03/91	26/03/91	1	2	1	50.0	98.5	1			
					30								
	248	Placabo	07/03/91	07/03/91	1	2	1	100.0	100.0	0	1	9m	
			08/03/91	21/03/91	14	2	2	100.0	100.0	1	1		
					15								
	249	Reboxetine	08/03/91	10/03/91	3	2	2	100.0	100.0	1	1	6e	
			11/03/91	11/03/91	1	2	1	50.0	87.5	1			
					4								
	250	Imipramine	12/03/91	07/04/91	27	2	2	100.0	100.0	1	1	6e	
			08/04/91	08/04/91	1	2	1	50.0	98.2	1			
					28								
	251	Imipramine	20/03/91	11/04/91	23	2	2	100.0	100.0	1	1	6e	
			12/04/91	12/04/91	1	2	1	50.0	97.9	1			
					24								
	252	Reboxetine	02/04/91	17/04/91	16	2	2	100.0	100.0	1	1		

1054

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

32

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 9.0
 EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cpl. day	Z Cumpl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (xx)
9	252	Reboxetine	18/04/91	20/04/91	3	2	1	100.0	1	1	3e	
					19							
	253	Reboxetine	02/04/91	07/04/91	6	2	2	100.0	1	1		
			08/04/91	08/04/91	1	2	1	50.0	1	1	6e	
					7							
	254	Inipramine	09/04/91	15/04/91	7	2	2	100.0	1	1		
			16/04/91	16/04/91	1	2	1	50.0	1	1	6e	
					8							
	255	Reboxetine	13/05/91	05/06/91	24	2	2	100.0	1	1		
			06/06/91	06/06/91	1	2	1	50.0	1	1	6e	
					25							
	256	Inipramine	27/05/91	05/06/91	10	2	2	100.0	1	1		
			06/06/91	09/06/91	4	2	1	100.0	1	1	3e	
			10/06/91	10/06/91	1	2	1	100.0	1	0	3	
			11/06/91	16/06/91	6	2	1	100.0	1	1	3e	
			17/06/91	20/06/91	4	2	2	100.0	1	1		
			21/06/91	08/07/91	18	2	1	100.0	1	1	3e	
					43							
	257	Placebo	25/06/91	30/06/91	6	2	2	100.0	1	1		
			01/07/91	01/07/91	1	2	1	50.0	1	1	6e	
					7							
	258	Placebo	01/07/91	09/07/91	9	2	2	100.0	1	1		
			10/07/91	10/07/91	1	2	1	50.0	1	1	6e	
					10							
11	319	Placebo	02/08/91	12/09/91	42	2	2	100.0	1	1		
					42							
	320	Inipramine	17/08/91	27/08/91	11	2	2	100.0	1	1		

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 m = morning, e = evening

9550082

33

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% compl. day	% cumulat.	Morning Cps	Afternoon Cps	Reason (x)	Overdose (xx)			
11	320	Imipramine	28/08/91	28/08/91	1	2	1	50.0	95.8		1		1m			
			29/08/91	01/09/91	4	2	2	100.0	96.9		1					
			02/09/91	02/09/91	1	2	1	50.0	94.1		1		4e			
			03/09/91	03/09/91	1	2	1	50.0	91.7		1		4m			
			04/09/91	25/09/91	22	2	2	100.0	96.3		1					
			26/09/91	26/09/91	1	2	1	100.0	96.3		1		0	9e		
								41								
			06/09/91	16/10/91	41	2	2	100.0	100.0		1		1		9e	
			17/10/91	17/10/91	1	2	1	100.0	100.0		1		0			
								42								
			322	Reboxetine	27/09/91	06/11/91	41	2	2	100.0	100.0		1		1	
07/11/91	07/11/91	1			2	1	100.0	100.0		1		0	9e			
					42											
323	Reboxetine	15/11/91	25/12/91	41	2	2	100.0	100.0		1		1				
		26/12/91	26/12/91	1	2	1	100.0	100.0		1		0	9e			
					42											
324	Imipramine	06/12/91	15/01/92	41	2	2	100.0	100.0		1		1				
		16/01/92	16/01/92	1	2	1	100.0	100.0		1		0	9e			
					42											
325	Reboxetine	13/12/91	18/12/91	6	2	2	100.0	100.0		1		1				
		19/12/91	19/12/91	1	2	1	50.0	92.9		1			10e			
		20/12/91	26/12/91	7	2	2	100.0	96.4		1		1				
		27/12/91	27/12/91	1	2	1	75.0	95.0		1		0	1			
		28/12/91	22/01/92	26	2	2	100.0	98.2		1		1				
		23/01/92	23/01/92	1	2	1	100.0	98.2		1		0	9e			
							42									
326	Placebo	16/01/92	16/01/92	1	2	1	100.0	100.0		0		1	9m			
		17/01/92	20/02/92	35	2	2	100.0	100.0		1		1				
		21/02/92	21/02/92	1	2	0	0	97.3		1			10m 10e			
		22/02/92	26/02/92	5	2	2	100.0	97.6		1		1				
		27/02/92	27/02/92	1	2	1	100.0	97.7		1		0	9e			

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (xx) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration, 8= morning, 9 = evening

9550082

34

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z Compl. day	Z Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)														
11	327	Imipramine	30/01/92 05/02/92	04/02/92 05/02/92	6 1	2 2	2 1	100.0 50.0	100.0 92.9	1 1	1	6e															
														43													
														7													
														328	Imipramine	31/01/92 05/02/92	04/02/92 05/02/92	5 1	2 2	2 2	100.0 50.0	100.0 91.7	1 1	1	3m 6e		
																											6
																											41
														329	Placebo	10/04/92 21/05/92	20/05/92 21/05/92	41 1	2 2	2 1	100.0 100.0	100.0 100.0	1 1	0	9e		
42																											
330	Reboxetine		09/04/92 10/04/92	09/04/92 13/05/92	1 34	2 2	100.0 100.0	100.0 100.0	0 1	1	1	9m															
														43													
														14/05/92													
														15/05/92													
														17/05/92													
														18/05/92													
														21/05/92													
														43													
														41													
														42													
331	Imipramine	17/04/92 28/05/92	27/05/92 28/05/92	41 1	2 2	2 1	100.0 100.0	100.0 100.0	1 1	0	1	9e															
														42													
														41													
332	Reboxetine	19/05/92 29/06/92	28/06/92 29/06/92	41 1	2 2	2 1	100.0 100.0	100.0 100.0	1 1	0	1	9e															
														42													
333	Placebo	27/05/92 07/07/92	06/07/92 07/07/92	41 1	2 2	2 1	100.0 100.0	100.0 100.0	1 1	0	1	9e															
														42													

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, 6=high daily dose in one administration, 7=low daily dose in one administration
 n = morning, o = evening

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35

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	% day	Cumpl. cumulat.	%	Morning Cps	Afternoon Cps	Reason (±)	Overdose (xx)
11	334	Reboxetine	29/05/92	31/05/92	3	2	2	100.0	100.0	100.0	1	1		
			01/06/92	01/06/92	1	2	2	50.0	87.5				3m 6e	
					4									
	335	Placebo	03/06/92	13/07/92	41	2	2	100.0	100.0	100.0	1	1		
			14/07/92	14/07/92	1	2	1	100.0	100.0				9e	
					42									
	336	Imipramine	18/06/92	18/06/92	1	2	1	100.0	100.0	100.0	0	1		9m
			19/06/92	24/06/92	6	2	2	100.0	100.0					
			25/06/92	25/06/92	1	2	1	50.0	93.8				6e	
					8									
	337	Reboxetine	02/07/92	02/07/92	1	2	1	100.0	100.0	100.0	0	1		9m
03/07/92			15/07/92	13	2	2	100.0	100.0						
16/07/92			16/07/92	1	2	1	75.0	98.3				1		
17/07/92			12/08/92	27	2	2	100.0	99.4						
13/08/92			13/08/92	1	2	1	100.0	99.4				9e		
				43										
338	Imipramine	23/07/92	23/07/92	1	2	1	100.0	100.0	100.0	0	1		9m	
		24/07/92	29/07/92	6	2	2	100.0	100.0						
		30/07/92	30/07/92	1	2	1	50.0	93.8				6e		
12	367	Reboxetine	20/12/91	20/12/91	1	2	1	100.0	100.0	100.0	0	1		9m
			21/12/91	30/01/92	41	2	2	100.0	100.0					
				42										
368	Placebo	24/12/91	24/12/91	1	2	1	100.0	100.0	100.0	0	1		9m	
		25/12/91	03/02/92	41	2	2	100.0	100.0						
				42										
369	Imipramine	23/06/92	12/05/92	20	2	2	100.0	100.0	100.0	1	1		6s	
		13/05/92	13/05/92	1	2	1	50.0	97.6						

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
 (**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
 m = morning, e = evening

1058

9550082

36

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. %	X Cumulat. compl. %	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)						
12	370	Placebo	25/04/92 20/05/92	19/05/92 20/05/92	21 1	2 2	100.0 50.0	100.0 97.7	1 1	1	6e							
													22	2	100.0	1	1	
371	371	Imipramine	01/05/92	06/05/92	6	2	100.0	100.0	1	1								
													6	2	100.0	1	1	
372	372	Reboxetine	02/06/92 03/06/92	02/06/92 13/07/92	41	2	100.0	100.0	0	1	9m							
													42	2	100.0	1	1	
373	373	Reboxetine	05/06/92 06/06/92 14/07/92	05/06/92 13/07/92 14/07/92	38	2	100.0	100.0	0	1	9m							
													39	2	100.0	1	1	
													40	2	50.0	98.8	1	6e
374	374	Placebo	09/06/92 06/07/92	05/07/92 06/07/92	27	2	100.0	100.0	1	1	6e							
													28	2	50.0	98.2	1	
375	375	Imipramine	17/06/92 18/06/92	17/06/92 18/06/92	1	2	100.0	100.0	1	1	6e							
													2	2	50.0	75.0	1	
13	13	Placebo	13/04/91	24/05/91	42	2	100.0	100.0	1	1								
													42	2	100.0	100.0	1	1
14	14	Placebo	02/07/91 23/07/91 24/07/91	22/07/91 23/07/91 13/08/91	21	2	100.0	100.0	1	1	1e							
													21	2	50.0	97.7	1	
													43	2	100.0	98.8	1	1

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

1059

9550082

37

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z Cumpl. day	Z Cumpl. Morning Cps	Morning Afternoon Cps	Reason (*)	Overdose (**)
13	15	Imipramine	05/07/91	15/08/91	42	2	2	100.0	100.0	1	1	
					42							
					42							
16	Imipramine	03/12/91	05/12/91	3	2	2	100.0	100.0	1	1	3m 3e	
				40	2	2	100.0	100.0				
				32	2	2	100.0	100.0	1	1		
				45								
				45								
17	Reboxetine	21/05/92	01/06/92	12	2	2	100.0	100.0	1	1		
				1	2	2	50.0	96.2	1	1	10e	
				14	2	2	100.0	98.1	1	1		
				7	2	2	0.0	77.9				
				8	2	2	100.0	82.1	1	1		
				42								
				42								
18	Reboxetine	24/06/92	02/08/92	40	2	2	100.0	100.0	1	1		
				40								
409	Reboxetine	10/12/91	20/12/91	11	2	2	100.0	100.0	1	1		
				3	2	2	0.0	78.6			4m 4e	
				28	2	2	100.0	92.9	1	1		
				42								
410	Placebo	14/02/92	20/02/92	7	2	2	100.0	100.0	1	1		
				1	2	2	0.0	87.5			10m 10e	
				34	2	2	100.0	97.6	1	1		
411	Imipramine	28/03/92	08/05/92	42	2	2	100.0	100.0	1	1		
				42								
423	Placebo	14/09/92	27/10/92	44	2	2	100.0	100.0	1	1		
				44								
14	Reboxetine	10/04/92	06/05/92	27	2	2	100.0	100.0	1	1		
				27								
				44								

1060

(*) 1=forgot to take, 2=lost medication, 3=advance event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/and treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
n = morning, e = evening

9550082

38

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z Compl. day	X Compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
					27								
14	20	Imipramine	29/04/92	29/04/92	1	2	2	100.0	100.0	1	1		
			30/04/92	30/04/92	1	2	2	100.0	100.0			3m 3e	
			01/05/92	09/06/92	40	2	2	100.0	100.0	1	1		
					42								
21		Imipramine	20/07/92	20/07/92	1	2	1	100.0	100.0	0	1	9m	
			21/07/92	22/08/92	33	2	2	100.0	100.0	1	1		
			23/08/92	23/08/92	1	2	1	50.0	98.6	1	1	4m	
			24/08/92	24/08/92	1	2	1	50.0	97.2	1	1	6e	
					36								
15	25	Reboxetine	18/06/91	18/06/91	1	2	1	100.0	100.0	0	1	9m	
			19/06/91	29/07/91	41	2	2	100.0	100.0	1	1		
					42								
26		Placebo	20/06/91	20/06/91	1	2	1	100.0	100.0	0	1	9m	
			21/06/91	26/06/91	6	2	2	100.0	100.0	1	1		
			27/06/91	27/06/91	1	2	1	50.0	98.8	1	1	1m	
			28/06/91	31/07/91	34	2	2	100.0	98.8	1	1		
			01/08/91	01/08/91	1	2	1	100.0	98.8	1	0	9e	
					43								
27		Imipramine	02/07/91	29/07/91	28	2	2	100.0	100.0	1	1		
			30/07/91	30/07/91	1	2	1	50.0	98.3	1	1	1e	
			31/07/91	12/08/91	13	2	2	100.0	98.8	1	1		
			13/08/91	13/08/91	1	2	1	100.0	98.8	1	0	9e	
					43								
28		Reboxetine	08/08/91	09/09/91	33	2	2	100.0	100.0	1	1		
			10/09/91	10/09/91	1	2	1	50.0	98.5	1	1	1m	
			11/09/91	19/09/91	9	2	2	100.0	98.8	1	1		
					43								
29		Placebo	29/08/91	29/08/91	1	2	1	100.0	100.0	0	1	9m	

1061

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

39

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	Z compl. cumulat.	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)	
15	29	Placebo	30/08/91	18/09/91	20	2	2	100.0	1	1	6e		
			19/09/91	19/09/91	1	2	1	50.0	97.7	1			
30		Imipramine	22		5	2	2	100.0	1	1	10e		
			03/09/91	07/09/91	1	2	1	50.0	91.7	1			
			08/09/91	08/09/91	1	2	2	100.0	85.7	1			
			09/09/91	09/09/91	1	2	2	100.0	95.2	1			
			10/09/91	23/09/91	14	2	1	50.0	93.2	1			
			24/09/91	24/09/91	1	2	2	100.0	93.5	1			
			25/09/91	25/09/91	1	2	2	100.0	91.7	1			
			26/09/91	26/09/91	1	2	2	100.0	94.3	1			
			27/09/91	07/10/91	11	2	2	100.0	93.1	1			
			08/10/91	08/10/91	1	2	2	100.0	94.0	1			
			09/10/91	14/10/91	6	2	2	100.0	94.2	1			
			15/10/91	15/10/91	1	2	1	100.0	94.2	1			0
			43										
403		Imipramine	04/10/91	04/10/91	1	2	1	100.0	100.0	0	9m		
			05/10/91	13/11/91	40	2	2	100.0	100.0	1			
			14/11/91	14/11/91	1	2	1	100.0	100.0	1			
			42										
404		Reboxetine	08/10/91	08/10/91	1	2	1	100.0	100.0	0	9m		
			09/10/91	17/10/91	9	2	2	100.0	100.0	1			
			18/10/91	18/10/91	1	2	1	50.0	95.5	1			
			19/10/91	22/10/91	4	2	2	100.0	96.7	1			
			23/10/91	23/10/91	1	2	1	50.0	93.8	1			
			24/10/91	30/10/91	7	2	2	100.0	95.7	1			
			31/10/91	31/10/91	1	2	1	50.0	93.8	1			
			01/11/91	04/11/91	4	2	2	100.0	94.6	1			
			05/11/91	05/11/91	1	2	1	50.0	93.1	1			1
			29										
405		Placebo	11/11/91	11/11/91	1	2	1	100.0	100.0	0	9m		
			12/11/91	22/12/91	41	2	2	100.0	100.0	1			
			23/12/91	23/12/91	1	2	1	100.0	100.0	1			0
43													

(*) 1=forget to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

40

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Compl. Cps	Σ day	Σ compl. cumulat. Cps	Morning Cps	Afternoon Cps	Reason (*)	Overdose (**)
15	406	Imipramine	27/11/91	27/11/91	1	2	1	100.0	100.0	0	1	9h	
			28/11/91	06/01/92	40	2	2	100.0	100.0	1	1	9a	
			07/01/92	07/01/92	1	2	1	100.0	100.0	1	0		
42													
407	Reboxetine	03/12/91	03/12/91	1	2	1	100.0	100.0	100.0	0	1	9m	
		04/12/91	25/12/91	22	2	2	100.0	100.0	1	1			
		26/12/91	26/12/91	1	2	1	50.0	97.9	1	1	10m		
		27/12/91	10/01/92	15	2	2	100.0	98.7	1	1			
		11/01/92	11/01/92	1	2	0	0.0	96.3	2	2	1m		
		12/01/92	13/01/92	2	2	2	100.0	96.4	1	1			
		14/01/92	14/01/92	1	2	1	100.0	96.5	1	0	9a		
43													
408	Placebo	20/01/92	20/01/92	1	2	1	100.0	100.0	100.0	0	1	9m	
		21/01/92	03/03/92	43	2	2	100.0	100.0	1	1			
		04/03/92	04/03/92	1	2	1	100.0	100.0	1	0	9a		
45													
418	Placebo	30/01/92	30/01/92	1	2	1	100.0	100.0	100.0	0	1	9m	
		31/01/92	11/03/92	41	2	2	100.0	100.0	1	1			
		12/03/92	12/03/92	1	2	1	100.0	100.0	1	0	9a		
43													
419	Placebo	28/04/92	28/04/92	1	2	1	100.0	100.0	100.0	0	1	9m	
		29/04/92	01/05/92	3	2	2	100.0	100.0	1	1			
		02/05/92	02/05/92	1	2	1	50.0	90.0	1	1	1a		
		03/05/92	27/05/92	25	2	2	100.0	98.3	1	1			
		28/05/92	28/05/92	1	2	1	50.0	96.8	1	1	1m		
		29/05/92	29/05/92	1	2	2	100.0	96.9	1	1			
		30/05/92	30/05/92	1	2	1	50.0	95.5	1	1	1a		
		31/05/92	08/06/92	9	2	2	100.0	96.4	1	1			
		09/06/92	09/06/92	1	2	1	100.0	96.5	1	0	9a		
		43											

1063

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown
(**) 1=low dose, 2=high dose, 3=low dose + high dose, 4=double high dose, 8=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Sequen. block	Given		Start treat. date	Patient	Patient	Randomized		Error (#)	
		Treatment	Treatment				Treatment	Sequen. block		
1	1	Imipramine	1	18/04/91	1	1	Imipramine	1		
	1	Reboxetine	2	15/04/91	2	2	Reboxetine	1		
	1	Imipramine	3	06/05/91	3	3	Imipramine	1		
	1	Placebo	4	23/05/91	6	4	Placebo	1		
	1	Reboxetine	5	04/06/91	4	5	Reboxetine	1	*	
	2	Placebo	6	12/06/91	5	6	Placebo	1	*	
	2	Reboxetine	7	27/08/91	7	7	Reboxetine	2		
	2	Placebo	8	05/09/91	8	8	Placebo	2		
	2	Imipramine	9	24/09/91	10	9	Reboxetine	2	*	
	2	Reboxetine	10	10/10/91	11	10	Placebo	2	*	
	3	Imipramine	11	18/10/91	12	11	Imipramine	2		
	3	Reboxetine	12	13/11/91	412	12	Reboxetine	2	*	
	4	Placebo	9	09/12/91	413	412	Placebo	3		
	4	Imipramine	413	14/01/92	414	413	Imipramine	3		
	4	Reboxetine	414	17/01/92	415	414	Reboxetine	4	*	
5	Imipramine	415	22/01/92	416	415	Imipramine	4	*		
5	Reboxetine	416	27/02/92	417	416	Reboxetine	4	*		
5	Imipramine	417	05/08/92	421	417	Imipramine	4	*		
5	Reboxetine	418		422	418	Placebo	4	*		
2/1	1	Placebo	49	18/05/91	49	49	Placebo	1		
	1	Reboxetine	50	27/12/91	50	50	Reboxetine	1		
	1	Imipramine	51	02/02/92	51	51	Imipramine	1		
2/2	1	Imipramine	43	18/04/91	43	43	Imipramine	1		
	1	Imipramine	44	19/07/91	44	44	Imipramine	1		
	1	Reboxetine	45	08/09/91	45	45	Reboxetine	1		
	1	Placebo	46	26/09/91	46	46	Placebo	1		
	1	Placebo	47	24/03/92	47	47	Placebo	1		
	1	Reboxetine	48	07/04/92	48	48	Reboxetine	1		
2/3	1	Imipramine	36/A	07/03/91	36/A	37	Reboxetine	2	*	
	2	Reboxetine	37	27/03/91	37	38	Placebo	2	*	
	2	Imipramine	39	10/08/91	39	39	Imipramine	2		
	2	Placebo	40	14/08/91	40	40	Reboxetine	2	*	
	2	Placebo	41	03/10/91	41	41	Placebo	2		
	2	Reboxetine	42	24/10/91	42	42	Imipramine	2	*	
	2	Imipramine	42	19/05/92	42	42	Out of Ramdo	2	*	
	2/4	1	Placebo	31	26/03/91	31	31	Placebo	1	
	1	Imipramine	32	29/05/91	32	32	Reboxetine	1	*	
	1	Reboxetine	33	26/10/91	33	33	Imipramine	1	*	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Randomized		Error (x)
	Sequen. block	Treatment			Treatment	Sequen. block	
2/4	1	Imipramine	12/02/92	36	34	Placebo	1
	1	Placebo	17/04/92	34	35	Reboxetine	1
	1	Reboxetine	15/09/92	35	36	Imipramine	1
2/5	1	Placebo	07/02/92	73	73	Placebo	1
	1	Reboxetine	21/06/92	74	74	Reboxetine	1
	1	Imipramine	11/09/92	75	75	Imipramine	1
	1	Placebo	15/09/92	76	76	Imipramine	1
	1	Reboxetine	22/09/92	77	77	Placebo	1
2/6	1	Imipramine	05/05/92	57	55	Reboxetine	1
	1	Placebo	12/05/92	60	56	Reboxetine	1
	1	Reboxetine	18/05/92	58	57	Imipramine	1
	1	Placebo	27/05/92	58	58	Placebo	1
	1	Reboxetine	12/06/92	55	59	Placebo	1
	1	Reboxetine	12/06/92	56	60	Imipramine	1
3/1	1	Imipramine	05/03/91	61	61	Imipramine	1
	1	Placebo	14/03/91	64	62	Imipramine	1
	1	Imipramine	16/04/91	62	63	Placebo	1
	1	Placebo	13/05/91	63	64	Placebo	1
	1	Reboxetine	10/06/91	66	65	Reboxetine	1
	2	Imipramine	03/09/91	139	66	Reboxetine	1
	2	Placebo	12/09/91	140	139	Imipramine	2
	1	Reboxetine	16/09/91	65	140	Placebo	2
	2	Placebo	03/10/91	141	141	Placebo	2
	2	Imipramine	18/11/91	142	142	Imipramine	2
	3	Reboxetine	20/01/92	451	143	Reboxetine	2
	3	Placebo	22/01/92	452	144	Reboxetine	2
	3	Imipramine	29/01/92	453	451	Reboxetine	3
	3	Reboxetine	17/02/92	454	452	Placebo	3
3	Placebo	11/03/92	455	453	Imipramine	3	
2	Imipramine	25/03/92	456	454	Reboxetine	3	
2	Reboxetine	15/04/92	143	455	Placebo	3	
2	Reboxetine	09/06/92	144	456	Imipramine	3	
3/2	1	Reboxetine	29/01/91	65/A		Out of Rando	x
3/3	1	Placebo	18/07/91	67	67	Placebo	1
	1	Reboxetine	21/01/92	68	68	Reboxetine	1

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PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized		Error (*)
	Sequen. block	Treatment				Treatment	Sequen. block	
3/3	1	Placebo	04/02/92	69	69	Placebo	1	
	1	Imipramine	15/04/92	70	70	Imipramine	1	
	1	Imipramine	16/04/92	71	71	Imipramine	1	
	1	Reboxetine	25/07/92	72	72	Reboxetine	1	
3/4	1	Imipramine	04/05/91	79	79	Imipramine	1	
	1	Reboxetine	17/05/91	81	80	Imipramine	1	*
	1	Placebo	17/06/91	82	81	Reboxetine	1	*
	1	Placebo	17/06/91	83	82	Reboxetine	1	*
	1	Imipramine	01/09/91	80	83	Placebo	1	
	1	Reboxetine	09/10/91	84	84	Reboxetine	1	
	2	Imipramine	29/10/91	85	85	Imipramine	2	
	2	Imipramine	03/12/91	86	86	Imipramine	2	
	2	Placebo	09/12/91	87	87	Placebo	2	
	2	Placebo	23/03/92	88	88	Placebo	2	
	2	Reboxetine	26/03/92	89	89	Reboxetine	2	
	2	Reboxetine	28/04/92	90	90	Reboxetine	2	
	3	Placebo	22/05/92	457	457	Placebo	3	
	3	Reboxetine	26/05/92	458	458	Reboxetine	3	
	3	Placebo	02/06/92	459	459	Placebo	3	
	3	Reboxetine	13/08/92	460	460	Reboxetine	3	
3	Imipramine	17/03/92	461	461	Imipramine	3		
3	Imipramine	29/03/92	462	462	Imipramine	3		
4/1	1	Placebo	03/06/91	119	115	Reboxetine	1	*
	2	Imipramine	03/07/91	95	116	Imipramine	1	
	2	Placebo	05/07/91	93	117	Imipramine	1	*
	2	Reboxetine	07/08/91	94	118	Reboxetine	1	*
	1	Imipramine	03/09/91	92	119	Placebo	1	*
	2	Imipramine	04/09/91	117	120	Placebo	1	*
	2	Imipramine	12/10/91	96	91	Imipramine	2	*
	1	Reboxetine	06/05/92	115	93	Reboxetine	2	*
	1	Imipramine	16/05/92	116	94	Placebo	2	*
	1	Reboxetine	23/05/92	118	95	Imipramine	2	*
	1	Placebo	31/07/92	120	96	Reboxetine	2	*
	3	Reboxetine	01/09/92	147	145	Imipramine	3	*
	3	Placebo	16/09/92	146	146	Placebo	3	
	3	Imipramine	26/09/92	148	147	Reboxetine	3	*
	3	Imipramine	30/09/92	145	148	Imipramine	3	
	3	Reboxetine	30/09/92	149	149	Reboxetine	3	
3	Placebo	30/09/92	150	150	Placebo	3		

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized		Error (*)	
	Sequen. block	Treatment				Treatment	Sequen. block		
4/2	1	Placebo	22/02/91	93/A	104	Reboxetine	2	*	
	1	Placebo	27/03/91	99/A	105	Placebo	2		
	2	Reboxetine	22/05/91	104	106	Imipramine	2	*	
4/3	1	Placebo	17/04/91	97	97	Placebo	1		
	1	Reboxetine	20/06/91	98	98	Reboxetine	1		
	1	Placebo	08/08/91	99	99	Placebo	1		
	1	Imipramine	27/11/91	100	100	Imipramine	1		
	1	Imipramine	17/03/92	101	101	Imipramine	1		
4/4	1	Reboxetine	08/06/91	109	109	Reboxetine	1		
	1	Imipramine	15/06/91	110	110	Imipramine	1		
	1	Imipramine	04/07/91	111	111	Imipramine	1		
	1	Placebo	10/07/91	112	112	Placebo	1		
	1	Reboxetine	31/08/91	113	113	Reboxetine	1		
	1	Placebo	20/11/91	114	114	Placebo	1		
	2	Imipramine	13/02/92	175	175	Imipramine	2		
	2	Placebo	14/03/92	176	176	Placebo	2		
	2	Reboxetine	28/04/92	177	177	Reboxetine	2		
	2	Placebo	11/09/92	179	179	Placebo	2		
	2	Reboxetine	07/10/92	180	180	Reboxetine	2		
	5/1	1	Reboxetine	06/06/91	127	127	Reboxetine	1	
		1	Reboxetine	14/06/91	128	128	Reboxetine	1	
1		Placebo	24/12/91	129	129	Placebo	1		
1		Placebo	05/03/92	130	130	Placebo	1		
1		Imipramine	21/03/92	131	131	Imipramine	1		
5/2	1	Reboxetine	28/01/91	125	121	Imipramine	1	*	
	1	Imipramine	20/12/91	121	122	Placebo	1	*	
5/3	1	Placebo	29/11/91	133	133	Placebo	1		
	1	Reboxetine	06/12/91	134	134	Reboxetine	1		
	1	Imipramine	10/01/92	135	135	Imipramine	1		
	1	Imipramine	02/03/92	136	136	Imipramine	1		
	1	Reboxetine	15/05/92	137	137	Reboxetine	1		
1	Placebo	15/05/92	138	138	Placebo	1			

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Treatment	Randomized		Error (x)	
	Sequen. block	Treatment				Sequen. block	Treatment		
6/1	1	Reboxetine	18/03/91	153	151	Imipramine	1	*	
	1	Imipramine	21/01/92	151	152	Reboxetine	1	*	
	1	Reboxetine	24/02/92	152	153	Reboxetine	1		
	1	Imipramine	30/03/92	154	154	Imipramine	1		
6/2	1	Placebo	08/07/92	155	155	Placebo	1		
	1	Placebo	08/09/92	156	156	Placebo	1		
	1	Reboxetine	30/04/91	157	157	Reboxetine	1		
	1	Placebo	10/07/91	162	158	Imipramine	1	*	
6/3	1	Imipramine	14/07/91	159	159	Imipramine	1		
	2	Placebo	01/11/91	170	160	Placebo	1		
	1	Imipramine	24/11/91	158	161	Reboxetine	1	*	
	1	Placebo	26/11/91	160	162	Placebo	1		
	2	Imipramine	26/12/91	169	169	Imipramine	2		
	1	Reboxetine	20/02/92	161	170	Placebo	2	*	
	2	Placebo	11/05/92	174	171	Imipramine	2	*	
	2	Reboxetine	05/07/92	173	172	Reboxetine	2	*	
	2	Placebo	07/07/92	172	173	Placebo	2	*	
	2	Imipramine	22/07/92	171	174	Reboxetine	2	*	
	6/3	1	Reboxetine	06/06/91	163	163	Reboxetine	1	
		1	Imipramine	11/10/91	164	164	Imipramine	1	
1		Imipramine	16/10/91	165	165	Imipramine	1		
1		Reboxetine	25/10/91	166	166	Reboxetine	1		
1		Placebo	18/11/91	167	167	Placebo	1		
1		Placebo	03/12/91	168	168	Placebo	1		
2		Imipramine	03/12/91	505	505	Imipramine	2		
2		Placebo	08/01/92	506	506	Placebo	2		
2		Imipramine	14/01/92	507	507	Imipramine	2		
2		Reboxetine	05/02/92	508	508	Reboxetine	2		
2		Placebo	24/02/92	509	509	Placebo	2		
2		Reboxetine	27/02/92	510	510	Reboxetine	2		
7/02	3	Imipramine	19/03/92	511	511	Imipramine	3		
	3	Placebo	01/04/92	512	512	Placebo	3		
	3	Imipramine	13/05/92	513	513	Imipramine	3		
7/02	1	Placebo	23/11/91	182	181	Reboxetine	1	*	
	1	Imipramine	02/01/92	183	182	Placebo	1	*	
	1	Reboxetine	27/01/92	181	183	Imipramine	1	*	
	1	Imipramine	27/01/92	184	184	Imipramine	1		
	2	Reboxetine	10/04/92	185	183	Reboxetine	1		
	1	Placebo	15/04/92	535	186	Placebo	1		
1	Placebo	16/04/92	186	535	Placebo	2			

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized Treatment	Sequen. block	Error (*)
	Sequen. block	Treatment						
7/02	2	Reboxetine	08/05/92	536	536	Reboxetine	2	
7/03	1	Imipramine	18/02/92	187	187	Imipramine	1	
	1	Placebo	25/02/92	188	188	Placebo	1	
	1	Placebo	25/02/92	189	189	Placebo	1	
	1	Reboxetine	28/02/92	190	190	Reboxetine	1	
	1	Imipramine	03/03/92	191	191	Imipramine	1	
	1	Reboxetine	10/03/92	192	192	Reboxetine	1	
	2	Placebo	06/05/92	523	523	Placebo	2	
	2	Placebo	06/05/92	524	524	Placebo	2	
	2	Reboxetine	06/05/92	525	525	Reboxetine	2	
	2	Imipramine	06/05/92	526	526	Imipramine	2	
	2	Imipramine	19/05/92	527	527	Imipramine	2	
	2	Imipramine	19/05/92	528	528	Imipramine	2	
7/04	1	Placebo	25/01/92	193	193	Placebo	1	
	1	Reboxetine	25/01/92	194	194	Reboxetine	1	
	1	Placebo	25/01/92	195	195	Placebo	1	
	1	Reboxetine	01/02/92	196	196	Reboxetine	1	
	1	Imipramine	01/02/92	197	197	Imipramine	1	
	1	Imipramine	01/02/92	198	198	Imipramine	1	
	2	Placebo	28/03/92	199	199	Placebo	2	
	2	Reboxetine	28/03/92	200	200	Reboxetine	2	
	2	Reboxetine	28/03/92	201	201	Reboxetine	2	
	2	Placebo	04/04/92	202	202	Placebo	2	
	2	Placebo	04/04/92	203	203	Placebo	2	
	2	Imipramine	04/04/92	204	204	Imipramine	2	
7/05	1	Placebo	27/01/92	205	205	Placebo	1	
	1	Imipramine	28/01/92	206	206	Imipramine	1	
	1	Imipramine	28/01/92	207	207	Imipramine	1	
	1	Reboxetine	30/01/92	208	208	Reboxetine	1	
	1	Placebo	05/02/92	209	209	Placebo	1	
	1	Reboxetine	07/02/92	210	210	Reboxetine	1	
	2	Reboxetine	17/03/92	541	541	Reboxetine	2	
	2	Imipramine	17/03/92	542	542	Imipramine	2	
	2	Imipramine	18/03/92	543	543	Imipramine	2	
	2	Placebo	24/03/92	544	544	Placebo	2	
	2	Placebo	25/03/92	545	545	Placebo	2	
	2	Reboxetine	25/03/92	546	546	Reboxetine	2	
7/07	1	Placebo	18/02/92	529	529	Placebo	1	

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PHARMACIA CNS B&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized		Error (*)
	Sequen. block	Treatment				Treatment	Sequen. block	
7/07	1	Imipramine	20/02/92	530	530	Imipramine	1	
	1	Reboxetine	24/02/92	531	531	Reboxetine	1	
	1	Imipramine	27/04/92	532	532	Imipramine	1	
	1	Placebo	15/05/92	534	534	Placebo	1	
8	1	Reboxetine	13/05/91	211	211	Reboxetine	1	
	1	Placebo	14/09/91	212	212	Placebo	1	
	1	Imipramine	22/11/91	213	213	Imipramine	1	
	1	Placebo	18/02/92	214	214	Placebo	1	
	1	Imipramine	27/03/92	215	215	Imipramine	1	
	2	Reboxetine	30/03/92	217	217	Reboxetine	2	
	2	Placebo	09/04/92	218	218	Placebo	2	
	2	Imipramine	11/04/92	219	219	Imipramine	2	
	2	Placebo	27/04/92	220	220	Placebo	2	
	2	Imipramine	28/04/92	221	221	Imipramine	2	
	3	Placebo	11/05/92	222	222	Placebo	3	
	3	Imipramine	07/09/92	223	223	Imipramine	3	
	3	Placebo	11/09/92	224	224	Placebo	3	
	3	Reboxetine	23/09/92	225	225	Reboxetine	3	
	3	Imipramine	26/09/92	227	227	Imipramine	3	
	4	Reboxetine	28/09/92	228	228	Reboxetine	4	
4	Imipramine	30/09/92	229	229	Imipramine	4		
4	Placebo	02/10/92	231	231	Placebo	4		
4	Reboxetine	07/10/92	232	232	Reboxetine	4		
4	Placebo	07/10/92	233	233	Placebo	4		
4	Placebo	07/10/92	234	234	Placebo	4		
8/A	1	Placebo	14/10/92	235	235	Placebo	1	
	1	Reboxetine	14/10/92	236	236	Reboxetine	1	
	1	Imipramine	14/10/92	237	237	Imipramine	1	
	1	Placebo	15/10/92	238	238	Placebo	1	
	1	Imipramine	16/10/92	239	239	Imipramine	1	
	2	Placebo	16/10/92	240	240	Placebo	2	
	2	Reboxetine	16/10/92	241	241	Reboxetine	2	
	2	Imipramine	16/10/92	242	242	Imipramine	2	
	2	Placebo	16/10/92	243	243	Placebo	2	
	2	Imipramine	16/10/92	244	244	Imipramine	2	
9	1	Placebo	07/02/91	241	241	Placebo	1	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized		Error (x)	
	Sequen. block	Treatment				Treatment	Sequen. block		
9	1	Reboxetine	18/02/91	242	242	Reboxetine	1		
	1	Imipramine	19/02/91	244	243	Reboxetine	1	*	
	1	Reboxetine	20/02/91	243	244	Imipramine	1	*	
	1	Imipramine	22/02/91	245	245	Imipramine	1		
	2	Placebo	22/02/91	246	246	Placebo	1		
	2	Placebo	25/02/91	247	247	Placebo	2		
	2	Reboxetine	07/03/91	248	248	Placebo	2		
	2	Imipramine	08/03/91	249	249	Reboxetine	2		
	2	Imipramine	12/03/91	250	250	Imipramine	2		
	2	Reboxetine	20/03/91	251	251	Imipramine	2		
	3	Reboxetine	02/04/91	252	252	Reboxetine	2		
	3	Imipramine	02/04/91	253	253	Reboxetine	3		
	3	Imipramine	09/04/91	254	254	Imipramine	3		
	3	Reboxetine	13/05/91	255	255	Reboxetine	3		
	3	Imipramine	27/05/91	256	256	Imipramine	3		
	3	Placebo	25/06/91	257	257	Placebo	3		
	3	Placebo	01/07/91	258	258	Placebo	3		
	11	1	Placebo	02/08/91	319	319	Placebo	1	
		1	Imipramine	17/08/91	320	320	Imipramine	1	
		1	Placebo	06/09/91	321	321	Placebo	1	
1		Reboxetine	27/09/91	322	322	Reboxetine	1		
1		Imipramine	15/11/91	323	323	Reboxetine	1		
2		Reboxetine	06/12/91	324	324	Imipramine	1		
2		Placebo	13/12/91	325	325	Reboxetine	2		
2		Imipramine	16/01/92	326	326	Placebo	2		
2		Imipramine	30/01/92	327	327	Imipramine	2		
2		Reboxetine	31/01/92	328	328	Imipramine	2	*	
2		Placebo	09/04/92	330	329	Placebo	2	*	
3		Imipramine	10/04/92	329	330	Reboxetine	2		
3		Reboxetine	17/04/92	331	331	Imipramine	3		
3		Placebo	19/05/92	332	332	Reboxetine	3		
3		Reboxetine	27/05/92	333	333	Placebo	3		
3		Placebo	29/05/92	334	334	Reboxetine	3		
3		Imipramine	03/06/92	335	335	Placebo	3		
4		Imipramine	18/06/92	336	336	Imipramine	3		
4		Reboxetine	02/07/92	337	337	Reboxetine	4		
4		Imipramine	23/07/92	338	338	Imipramine	4		
12	1	Reboxetine	20/12/91	367	367	Reboxetine	1		
	1	Placebo	24/12/91	368	368	Placebo	1		
	1	Imipramine	23/04/92	369	369	Imipramine	1		
	1	Placebo	23/04/92	370	370	Placebo	1		
	1	Imipramine	01/05/92	371	371	Imipramine	1		

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 - (4) Assigned treatment different from randomized

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 10.0
 ASSIGNED vs RANDOMIZED TREATMENT

Centre	Sequen. block	Treatment	Given	Start treat. date	Patient	Treatment	Randomized	Sequen. block	Error (*)
12	1	Reboxetine		02/06/92	372	Reboxetine		1	
	2	Reboxetine		05/06/92	373	Reboxetine		2	
	2	Placebo		09/06/92	374	Placebo		2	
13	2	Imipramine		17/06/92	375	Imipramine		2	
	1	Placebo		13/04/91	13	Placebo		1	
	1	Placebo		02/07/91	14	Placebo		1	
	1	Imipramine		05/07/91	15	Imipramine		1	
	1	Imipramine		03/12/91	16	Imipramine		1	
	2	Reboxetine		10/12/91	409	Reboxetine		1	*
	2	Placebo		14/02/92	410	Reboxetine		1	*
	2	Imipramine		28/03/92	411	Reboxetine		2	*
	1	Reboxetine		21/05/92	17	Placebo		2	*
	1	Reboxetine		24/06/92	18	Imipramine		2	*
3	Placebo		14/09/92	423	Reboxetine		2	*	
14	1	Reboxetine		10/04/92	19	Reboxetine		1	
	1	Imipramine		29/04/92	20	Imipramine		1	
	1	Imipramine		20/07/92	21	Imipramine		1	
15	1	Reboxetine		18/06/91	25	Reboxetine		1	
	1	Placebo		20/06/91	26	Placebo		1	
	1	Imipramine		02/07/91	27	Imipramine		1	
	1	Reboxetine		08/08/91	28	Reboxetine		1	
	1	Placebo		29/08/91	29	Placebo		1	
	2	Imipramine		03/09/91	30	Imipramine		1	
	2	Reboxetine		04/10/91	403	Imipramine		2	
	2	Placebo		08/10/91	404	Reboxetine		2	
	2	Imipramine		11/11/91	405	Placebo		2	
	2	Reboxetine		27/11/91	406	Imipramine		2	
3	Placebo		03/12/91	407	Reboxetine		2		
3	Placebo		20/01/92	408	Placebo		2		
3	Placebo		30/01/92	418	Placebo		3		
				28/04/92	419	Placebo		3	

(*) - (1) Start new block not with first patient of block
 - (2) Start new block without ending previous block
 - (3) Sequence error
 - (4) Assigned treatment different from randomized

9550082

1

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
1	1	Female	Day 42	22/05/91	YES			As prescribed
	2	Male	Day 42	27/05/91	YES			As prescribed
	3	Male	Day 42	16/06/91	YES			As prescribed
	4	Male	Day 42	16/07/91	YES			As prescribed
	5	Female	Day 21	02/07/91	NO	Deterioration	Patient	As prescribed
	6	Female	Day 42	05/07/91	NO	Adverse event	Patient	As prescribed
	7	Female	Day 42	08/10/91	YES			As prescribed
	8	Male	Day 42	19/10/91	YES			As prescribed
	9	Female	Day 42	06/01/92	YES			As prescribed
	10	Male	Day 42	04/11/91	YES			As prescribed
	11	Female	Day 7	19/10/91	NO	Adverse event	Physician Patient Others	As prescribed
	12	Female	Day 42	30/11/91	YES			As prescribed
	412	Male	Day 42	23/12/91	YES			As prescribed
	413	Male	Day 42	20/01/92	YES			As prescribed
	414	Female	Day 14	29/01/92	NO	Deterioration	Physician	As prescribed
	415	Male	Day 42	27/02/92	YES			As prescribed
	416	Female	Day 14	28/01/92	NO	Protocol violation	Physician	As prescribed

1073

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

9550082

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
1	416	Female	Day 14	28/01/92	NO	Intercurrent medical problem		
	421	Male	Day 42	09/04/92	YES			As prescribed
	422	Male	Day 42	17/09/92	YES			As prescribed
2/1	49	Female	Day 42	28/06/91	YES			As prescribed
	50	Female	Day 42	06/02/92	YES			As prescribed
	51	Female	Day 42	15/03/92	YES			As prescribed
2/2	43	Female	Day 35	16/05/91	NO	Protocol violation Improvement Patient uncooperative	Patient	Confirmed irregularities
	44	Female	Day 42	29/08/91	YES			Unknown
	45	Female	Day 42	20/10/91	YES			As prescribed
	46	Female	Day 28	23/10/91	NO	Protocol violation Patient uncooperative	Physician	Confirmed irregularities
	47	Female	Day 42	04/05/92	YES			As prescribed
	48	Female	Day 42	19/05/92	YES			As prescribed
2/3	36/A	Male	Day 42	17/04/91	YES			As prescribed
	37	Female	Day 42	07/05/91	YES			As prescribed
	38	Male	Day 42	25/09/91	YES			As prescribed
	39	Female	Day 42	20/09/91	YES			As prescribed

1074

9550082

3

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOMETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
2/3	40	Female	Day 42	04/12/91	YES			As prescribed
	41	Male	Day 42	13/11/91	YES			As prescribed
	42	Female	Day 42	30/06/92	YES			As prescribed
2/4	31	Male	Day 42	05/05/91	YES			As prescribed
	32	Male	Day 42	06/12/91	YES			As prescribed
	33	Male	Day 42	10/07/91	YES			As prescribed
	34	Female	Day 42	28/05/92	YES			As prescribed
	35	Female	Day 42	26/10/92	YES			As prescribed
	36	Female	Day 42	24/03/92	YES			As prescribed
2/5	73	Male	Day 42	20/03/92	YES			As prescribed
	74	Male	Day 42	01/08/92	YES			As prescribed
	75	Male	Day 42	22/10/92	YES			As prescribed
	76	Female	Day 42	26/10/92	YES			As prescribed
	77	Male	Day 42	02/11/92	YES			As prescribed
	78	Female	Day 35	13/11/92	NO	Lost to follow up Patient uncooperative	Others	As prescribed
2/6	55	Female	Day 42	23/07/92	YES			As prescribed
	56	Female	Day 42	23/07/92	YES			As prescribed

1035

9550082

4

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
2/6	57	Female	Day 42	15/06/92	YES			As prescribed
	58	Female	Day 42	29/06/92	YES			As prescribed
	59	Male	Day 28	23/06/92	NO	Deterioration	Physician	As prescribed
	60	Female	Day 42	22/06/92	YES			As prescribed
3/1	61	Male	Day 35	08/06/91	NO	Patient uncooperative	Physician Patient	Suspected irregularities
	62	Female	Day 42	26/05/91	YES			As prescribed
	63	Male	Day 42	23/06/91	YES			As prescribed
	64	Female	Day 42	24/04/91	YES			As prescribed
	65	Male	Day 42	27/10/91	YES			As prescribed
	66	Male	Day 42	21/07/91	YES			As prescribed
	139	Male	Day 14	12/09/91	NO	Deterioration	Physician	As prescribed
	140	Male	Day 42	23/10/91	YES			As prescribed
	141	Female	Day 42	14/11/91	YES			As prescribed
	142	Female	Day 21	08/12/91	NO	Patient uncooperative	Patient	As prescribed
	143	Female	Day 35	20/05/92	NO	Adverse event Deterioration	Patient	As prescribed
	144	Female	Day 42	22/07/92	YES			As prescribed

1076

9550082

5

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Adverse event Lost to follow up	Decision to discontinue	Drug compliance
3/1	451	Female	Day 14	01/02/92	NO			Patient	As prescribed
	452	Male	Day 42	04/03/92	YES				As prescribed
	453	Female	Day 42	10/03/92	YES				As prescribed
	454	Male	Day 42	01/04/92	YES				As prescribed
	455	Female	Day 42	22/04/92	YES				As prescribed
	456	Female	Day 14	03/04/92	NO		Adverse event	Physician Patient	As prescribed
3/2	65/A	Female	Day 42	11/05/91	YES				As prescribed
3/3	67	Male	Day 42	28/06/91	YES				As prescribed
	68	Male	Day 42	02/03/92	YES				As prescribed
	69	Male	Day 42	16/03/92	YES				As prescribed
	70	Male	Day 42	26/05/92	YES				As prescribed
	71	Female	Day 42	27/05/92	YES				As prescribed
	72	Male	Day 42	04/09/92	YES				As prescribed
3/4	79	Female	Day 42	15/06/91	YES				As prescribed
	80	Male	Day 21	24/09/91	NO		Adverse event	Patient	As prescribed
	81	Female	Day 42	27/06/91	YES				As prescribed

1077

9550082

6

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 BEROXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
3/4	82	Male	Day 42	28/07/91	YES			As prescribed
	83	Male	Day 7	24/06/91	NO	Adverse event Deterioration	Physician	As prescribed
	84	Female	Day 42	23/11/91	YES			As prescribed
	85	Female	Day 42	08/12/91	YES			As prescribed
	86	Male	Day 42	15/01/92	YES			As prescribed
	87	Female	Day 42	19/01/92	YES			As prescribed
	88	Male	Day 42	08/05/92	YES			As prescribed
	89	Female	Day 42	06/05/92	YES			As prescribed
	90	Male	Day 42	08/06/92	YES			As prescribed
	457	Female	Day 21	11/06/92	NO	Deterioration	Physician	As prescribed
	458	Female	Day 14	09/06/92	NO	Deterioration Patient uncooperative	Patient	As prescribed
	459	Female	Day 42	13/07/92	YES			As prescribed
	460	Male	Day 7	20/08/92	NO	Adverse event	Physician Patient	As prescribed
	461	Female	Day 7	24/09/92	NO	Adverse event	Patient	As prescribed
	462	Female	Day 14	08/10/92	NO	Adverse event	Patient	As prescribed
4/1	91	Female	Day 42	22/11/91	YES			As prescribed

1078

9550082

7

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0
 REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete last dose as protocol	Reason	Decision to discontinue	Drug compliance
4/1	92	Female	Day 42	17/09/91	YES			As prescribed
	93	Male	Day 42	16/08/91	YES			As prescribed
	94	Female	Day 42	13/08/91	YES			As prescribed
	95	Female	Day 42	16/07/91	YES			As prescribed
	96	Female	Day 42	16/10/91	YES			As prescribed
	115	Female	Day 42	16/06/92	YES			As prescribed
	116	Female	Day 7	22/05/92	NO	Adverse event	Patient	As prescribed
	117	Female	Day 42	14/10/91	YES			As prescribed
	118	Female	Day 42	03/07/92	YES			As prescribed
	120	Female	Day 42	11/09/92	YES			As prescribed
	145	Female	Day 42	10/11/92	YES			As prescribed
	146	Female	Day 42	27/10/92	YES			As prescribed
	147	Female	Day 42	12/10/92	YES			As prescribed
	148	Female	Day 42	06/11/92	YES			As prescribed
	149	Male	Day 42	10/11/92	YES			As prescribed
	150	Male	Day 42	10/11/92	YES			As prescribed
4/2	93/A	Male	Day 42	04/04/91	YES			As prescribed

1079

9550082

8

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 KEBONETINE - PROTOCOL 20124/015
 LISTING No.: 11.0
 REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
4/2	99/A	Male	Day 42	07/05/91	YES			As prescribed
	104	Male	Day 42	02/07/91	YES			As prescribed
4/3	97	Male	Day 42	28/05/91	YES			As prescribed
	98	Female	Day 35	21/07/91	NO	Patient uncooperative	Patient	Suspected irregularities
	99	Female	Day 14	15/08/91	NO	Adverse event	Physician Patient	As prescribed
	100	Female	Day 21	17/12/91	NO	Adverse event Deterioration	Physician Patient	As prescribed
	101	Male	Day 42	27/04/92	YES			As prescribed
4/4	109	Female	Day 42	19/07/91	YES			As prescribed
	110	Male	Day 42	26/07/91	YES			As prescribed
	111	Male	Day 42	14/08/91	YES			As prescribed
	112	Male	Day 42	20/08/91	YES			As prescribed
	113	Male	Day 42	11/10/91	YES			As prescribed
	114	Female	Day 42	31/12/91	YES			As prescribed
	175	Female	Day 42	25/03/92	YES			As prescribed
	176	Female	Day 28	08/04/92	NO	Adverse event Deterioration	Physician	As prescribed
	177	Female	Day 21	11/05/92	NO	Deterioration	Physician	As prescribed

1080

9550082

9

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REMOXTINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
4/4	177	Female	Day 21	11/05/92	NO		Patient	
	178	Female	Day 42	08/06/92	YES			As prescribed
	179	Female	Day 21	29/09/92	NO	Adverse event Deterioration	Physician	As prescribed
	180	Male	Day 42	17/11/92	YES			As prescribed
5/1	127	Male	Day 42	17/07/91	YES			As prescribed
	128	Female	Day 42	25/07/91	YES			As prescribed
	129	Male	Day 42	03/02/92	YES			Suspected irregularities
	130	Male	Day 42	15/04/92	YES			As prescribed
	131	Female	Day 42	30/04/92	YES			As prescribed
	132	Male	Day 42	06/08/92	YES			As prescribed
5/2	121	Female	Day 42	27/01/92	NO	Deterioration	Physician	As prescribed
	125	Male	Day 42	10/03/91	YES			As prescribed
5/3	133	Male	Day 14	12/12/91	NO	Deterioration	Physician	As prescribed
	134	Female	Day 42	16/01/92	YES			As prescribed
	135	Female	Day 42	20/02/92	YES			As prescribed
	136	Female	Day 42	12/04/92	YES			As prescribed
	137	Female	Day 42	25/06/92	YES			As prescribed

1081

9550082

10

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REBOMETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose as protocol	Complete as protocol	Reason	Decision to discontinue	Drug compliance
5/3	138	Female	Day 7	16/05/92	NO	Intercurrent medical problem	Physician	As prescribed
6/1	151	Male	Day 7	28/01/92	NO	Adverse event	Physician	As prescribed
	152	Female	Day 42	07/04/92	YES			As prescribed
	153	Male	Day 42	29/04/91	YES			As prescribed
	155	Male	Day 28	04/08/92	NO	Deterioration Other	Physician	As prescribed
	156	Female	Day 42	19/10/92	YES			As prescribed
	157	Male	Day 42	10/06/91	YES			As prescribed
	158	Female	Day 42	05/01/92	YES			As prescribed
	159	Male	Day 42	24/08/91	YES			As prescribed
	160	Male	Day 42	04/01/92	YES			As prescribed
	161	Female	Day 28	18/03/92	NO	Intercurrent medical problem	Patient	As prescribed
	162	Male	Day 7	13/07/91	NO	Patient uncooperative	Patient	Suspected irregularities
	169	Female	Day 21	15/01/92	NO	Deterioration	Physician Patient	As prescribed
	170	Male	Day 14	15/11/91	NO	Deterioration	Patient	As prescribed
	171	Female	Day 42	01/09/92	YES			As prescribed
	172	Female	Day 42	17/08/92	YES			As prescribed

1082

9550082

11

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
6/2	173	Male	Day 42	15/08/92	YES			As prescribed
	174	Male	Day 42	21/06/92	YES			As prescribed
6/3	163	Male	Day 7	08/06/91	NO	Adverse event	Physician Patient	As prescribed
	164	Male	Day 42	21/11/91	YES			As prescribed
	165	Female	Day 42	26/11/91	YES			As prescribed
	166	Female	Day 7	29/10/91	NO	Deterioration	Physician	As prescribed
	167	Female	Day 42	27/12/91	YES			As prescribed
	168	Female	Day 35	06/01/92	NO	Deterioration	Physician	As prescribed
	505	Female	Day 14	17/12/91	NO	Deterioration	Physician Patient	As prescribed
	506	Female	Day 42	19/02/92	YES			Suspected irregularities
	507	Female	Day 42	24/02/92	YES			As prescribed
	508	Female	Day 42	17/03/92	YES			As prescribed
	509	Male	Day 42	06/04/92	YES			As prescribed
	510	Female	Day 14	10/03/92	NO	Adverse event	Physician Patient	As prescribed
	511	Female	Day 35	21/04/92	NO	Deterioration	Physician	As prescribed
	512	Female	Day 7	01/04/92	NO	Patient uncooperative	Patient	

1083

9550082

12

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose as protocol	Complete as protocol	Reason	Decision to discontinue	Drug compliance
6/3	513	Female	Day 42	23/06/92	YES			As prescribed
7/02	181	Male	Day 42	08/03/92	YES			As prescribed
	182	Male	Day 42	03/01/92	YES			As prescribed
	183	Male	Day 21	18/01/92	NO	Adverse event Patient uncooperative	Physician Patient	Confirmed irregularities
	184	Female	Day 42	08/03/92	YES			As prescribed
	185	Male	Day 28	05/05/92	NO	Adverse event	Physician Patient	As prescribed
	186	Male	Day 42	27/05/92	YES			As prescribed
	535	Male	Day 42	26/05/92	YES			As prescribed
	536	Female	Day 42	18/06/92	YES			As prescribed
7/03	187	Female	Day 42	30/03/92	YES			As prescribed
	188	Male	Day 42	06/04/92	YES			As prescribed
	189	Male	Day 42	06/04/92	YES			As prescribed
	190	Male	Day 42	09/04/92	YES			As prescribed
	191	Female	Day 42	10/04/92	NO	Adverse event	Physician	As prescribed
	192	Female	Day 42	20/04/92	YES			As prescribed
	523	Female	Day 42	16/06/92	YES			As prescribed

1004

9550082

13

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS 888
 REBOXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete last dose as protocol	Reason	Decision to discontinue	Drug compliance
7/03	524	Female	Day 42	16/06/92	YES			As prescribed
	525	Female	Day 42	16/06/92	YES			As prescribed
	526	Female	Day 42	16/06/92	YES			Suspected irregularities
	527	Female	Day 42	29/06/92	YES			Confirmed irregularities
	528	Female	Day 35	22/06/92	NO	Patient uncooperative	Physician Patient	Suspected irregularities
7/04	193	Female	Day 42	06/03/92	YES			As prescribed
	194	Male	Day 42	06/03/92	YES			As prescribed
	195	Female	Day 42	06/03/92	YES			As prescribed
	196	Female	Day 42	13/03/92	YES			As prescribed
	197	Male	Day 42	13/03/92	YES			As prescribed
	198	Female	Day 42	13/03/92	YES			As prescribed
	199	Male	Day 42	08/05/92	YES			As prescribed
	200	Male	Day 42	08/05/92	YES			As prescribed
	201	Female	Day 42	08/05/92	YES			As prescribed
	202	Male	Day 42	15/05/92	YES			As prescribed
	203	Female	Day 42	15/05/92	YES			As prescribed

1085

9550082

14

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
7/04	204	Female	Day 42	15/05/92	YES			As prescribed
7/05	205	Male	Day 42	08/03/92	YES			As prescribed
	206	Female	Day 42	09/03/92	YES			As prescribed
	207	Female	Day 42	09/03/92	YES			As prescribed
	208	Male	Day 42	11/03/92	YES			As prescribed
	209	Male	Day 42	17/03/92	YES			As prescribed
	210	Male	Day 42	19/03/92	YES			As prescribed
	541	Female	Day 42	27/04/92	YES			As prescribed
	542	Male	Day 42	27/04/92	YES			As prescribed
	543	Male	Day 42	28/04/92	YES			As prescribed
	544	Female	Day 42	04/05/92	YES			As prescribed
	545	Male	Day 42	05/05/92	YES			As prescribed
	546	Female	Day 42	05/05/92	YES			As prescribed
7/07	529	Female	Day 42	30/03/92	YES			As prescribed
	530	Female	Day 21	09/03/92	NO	Patient uncooperative	Patient	Unknown
	531	Female	Day 42	05/04/92	YES			As prescribed
	532	Female	Day 42	07/06/92	YES			As prescribed

1086

9550082

15

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RSD
REBOXETINE - PROTOCOL 20124/015
LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
7/07	533	Male	Day 42	14/06/92	YES			As prescribed
	534	Female	Day 42	25/06/92	YES			As prescribed
8	211	Female	Day 14	26/05/91	NO	Patient uncooperative	Patient	As prescribed
	212	Female	Day 42	25/10/91	YES			As prescribed
	213	Male	Day 7	24/11/91	NO	Death		
	214	Female	Day 42	03/01/92	YES			As prescribed
	215	Female	Day 42	30/03/92	YES			As prescribed
	216	Male	Day 42	07/05/92	YES			As prescribed
	217	Female	Day 42	10/05/92	YES			As prescribed
	218	Female	Day 42	20/05/92	YES			As prescribed
	219	Female	Day 21	01/05/92	NO	Patient uncooperative	Patient	Suspected irregularities
	220	Female	Day 42	07/06/92	YES			As prescribed
	221	Male	Day 42	08/06/92	YES			As prescribed
	222	Female	Day 42	08/06/92	YES			As prescribed
	223	Female	Day 42	21/06/92	YES			As prescribed
	224	Female	Day 42	18/10/92	YES			As prescribed
	225	Male	Day 42	22/10/92	YES			As prescribed

1087

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16

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PHARMACIA CNS R&D
 REBOXYETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
8	226	Male	Day 42	03/11/92	YES			As prescribed
	227	Male	Day 42	05/11/92	YES			As prescribed
	228	Male	Day 7	02/10/92	NO	Deterioration Patient uncooperative	Physician Patient	As prescribed
	229	Female	Day 42	10/11/92	YES			As prescribed
	230	Female	Day 42	08/11/92	YES			As prescribed
	231	Male	Day 42	10/11/92	YES			As prescribed
	232	Male	Day 42	12/11/92	YES			As prescribed
	233	Female	Day 42	17/11/92	YES			As prescribed
	234	Female	Day 42	17/11/92	YES			As prescribed
	235	Female	Day 42	24/11/92	YES			As prescribed
8/A	236	Female	Day 42	24/11/92	YES			As prescribed
	237	Female	Day 42	24/11/92	YES			As prescribed
	238	Female	Day 42	24/11/92	YES			As prescribed
	239	Female	Day 42	26/11/92	YES			As prescribed
	240	Female	Day 42	26/11/92	YES			As prescribed
	553	Female	Day 42	26/11/92	YES			As prescribed
	554	Male	Day 42	26/11/92	YES			As prescribed

1088

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17

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PHARMACIA CNS R&D
 RENOMETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
8/A	555	Female	Day 42	26/11/92	YES			As prescribed
	556	Male	Day 42	26/11/92	YES			As prescribed
9	241	Female	Day 14	17/02/91	NO	Adverse event Deterioration	Physician Patient	As prescribed
	242	Female	Day 21	11/03/91	NO	Patient uncooperative	Patient	As prescribed
	243	Female	Day 14	06/03/91	NO	Protocol violation	Physician	Confirmed irregularities
	244	Female	Day 28	13/03/91	NO	Patient uncooperative	Patient	As prescribed
	245	Female	Day 42	04/04/91	YES			As prescribed
	246	Female	Day 28	17/03/91	NO	Adverse event	Physician	As prescribed
	247	Female	Day 28	26/03/91	NO	Deterioration	Physician	As prescribed
	248	Male	Day 14	21/03/91	NO	Deterioration	Physician	As prescribed
	249	Female	Day 7	11/03/91	NO	Patient uncooperative	Patient	As prescribed
	250	Female	Day 28	08/04/91	NO	Deterioration	Physician Patient	As prescribed
	251	Female	Day 28	12/04/91	NO	Other	Others	As prescribed
	252	Female	Day 21	20/04/91	NO	Adverse event Patient uncooperative	Patient	As prescribed
	253	Female	Day 7	08/04/91	NO	Adverse event Deterioration Patient uncooperative	Physician Patient	As prescribed

1089

9550082

18

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 RENOXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose as protocol	Complete as protocol	Reason	Decision to discontinue	Drug compliance
9	254	Female	Day 14	16/04/91	NO	Adverse event Patient uncooperative	Patient	As prescribed
	255	Female	Day 28	06/06/91	NO	Adverse event Deterioration	Physician	As prescribed
	256	Female	Day 42	08/07/91	YES			As prescribed
	257	Male	Day 7	01/07/91	NO	Patient uncooperative	Patient	As prescribed
	258	Male	Day 14	10/07/91	NO	Patient uncooperative	Patient	As prescribed
	319	Male	Day 42	12/09/91	YES			As prescribed
	320	Male	Day 42	26/09/91	YES			As prescribed
	321	Male	Day 42	17/10/91	YES			As prescribed
	322	Female	Day 42	07/11/91	YES			As prescribed
	323	Male	Day 42	26/12/91	YES			As prescribed
	324	Male	Day 42	16/01/92	YES			As prescribed
	325	Male	Day 42	23/01/92	YES			As prescribed
	326	Male	Day 42	27/02/92	YES			As prescribed
	327	Male	Day 7	05/02/92	NO	Patient uncooperative	Patient	Unknown
	328	Female	Day 7	04/02/92	NO	Patient uncooperative	Patient	Unknown
	329	Female	Day 42	21/05/92	YES			As prescribed

1090

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19

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RSD
 REMOXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
11	330	Male	Day 42	21/05/92	YES			As prescribed
	331	Male	Day 42	28/05/92	YES			As prescribed
	332	Male	Day 42	29/06/92	YES			As prescribed
	333	Male	Day 42	07/07/92	YES			As prescribed
	334	Female	Day 7	31/05/92	NO	Adverse event	Patient	
	335	Male	Day 42	14/07/92	YES			As prescribed
	336	Female	Day 7	25/06/92	NO	Patient uncooperative	Patient	Confirmed irregularities
	337	Female	Day 42	13/08/92	YES			As prescribed
	338	Male	Day 7	30/07/92	NO	Lost to follow up	Patient	Unknown
	367	Female	Day 42	30/01/92	YES			As prescribed
12	368	Female	Day 42	03/02/92	YES			As prescribed
	369	Female	Day 21	13/05/92	NO	Deterioration	Physician	As prescribed
	370	Male	Day 28	20/05/92	NO	Deterioration	Physician	As prescribed
	371	Female	Day 7	06/05/92	NO	Intercurrent medical problem	Physician	As prescribed
	372	Male	Day 42	13/07/92	YES			As prescribed
	373	Male	Day 42	14/07/92	YES			As prescribed
	374	Female	Day 28	05/07/92	NO	Deterioration	Physician	As prescribed

1091

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20

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
LISTING No.: 11.0
REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
12	374	Female	Day 28	05/07/92	NO		Patient	
	375	Male	Day 7	18/06/92	NO	Adverse event Deterioration	Physician Patient	As prescribed
13	13	Male	Day 42	24/05/91	YES			As prescribed
	14	Male	Day 42	13/08/91	YES			As prescribed
	15	Female	Day 42	15/08/91	YES			As prescribed
	16	Male	Day 42	16/01/92	NO	Adverse event Deterioration	Patient	Confirmed irregularities
1092	17	Male	Day 42	01/07/92	YES			Suspected irregularities
	18	Male	Day 42	02/08/92	YES			As prescribed
	409	Male	Day 42	20/01/92	YES			As prescribed
	410	Male	Day 42	26/03/92	YES			As prescribed
	411	Female	Day 42	08/05/92	YES			As prescribed
	423	Male	Day 42	27/10/92	YES			As prescribed
14	19	Female	Day 28	06/05/92	NO	Deterioration	Physician Patient	As prescribed
	20	Female	Day 42	09/06/92	YES			As prescribed
	21	Female	Day 35	24/08/92	NO	Deterioration	Physician Patient	As prescribed
15	25	Female	Day 42	29/07/91	YES			As prescribed

9550082

21

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 RESOXETINE - PROTOCOL 20124/015
 LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose as protocol	Complete as protocol	Reason	Decision to discontinue	Drug compliance
15	26	Male	Day 42	01/08/91	YES			As prescribed
	27	Female	Day 42	13/08/91	YES			As prescribed
	28	Female	Day 42	19/09/91	YES			As prescribed
	29	Male	Day 21	19/09/91	NO	Deterioration	Physician	As prescribed
	30	Female	Day 42	15/10/91	YES			As prescribed
	403	Female	Day 42	14/11/91	YES			As prescribed
	404	Female	Day 28	05/11/91	NO	Deterioration	Patient	As prescribed
	405	Female	Day 42	23/12/91	YES			As prescribed
	406	Male	Day 42	07/01/92	YES			As prescribed
	407	Female	Day 42	14/01/92	YES			As prescribed
	408	Female	Day 42	04/03/92	YES			As prescribed
	418	Female	Day 42	12/03/92	YES			As prescribed
	419	Female	Day 42	09/06/92	YES			As prescribed

1003

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42		
1	1	Imipramine	Female	01. DEPRESSED MOOD	4	4	4	4	1	2	2	1	1	1	1	1	1	0		
				02. GUILT	2	2	3	3	2	2	1	1	1	1	1	1	1	1	0	
				03. SUICIDE	2	2	3	3	2	2	1	2	2	2	2	2	2	2	2	0
				04. INSOMNIA EARLY	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	0
				05. INSOMNIA MIDDLE	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	0
				06. INSOMNIA LATE	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	0
				07. WORK AND ACTIVITIES	2	2	3	3	4	4	4	1	1	2	2	2	2	2	2	0
				08. RETARDATION	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	0
				09. AGITATION	1	1	1	1	4	4	4	2	2	2	2	2	2	2	2	0
				10. ANXIETY PSYCHIC	3	3	3	3	4	4	4	2	2	2	2	2	2	2	2	1
				11. ANXIETY SOMATIC	3	3	3	3	2	2	2	1	2	2	2	2	2	2	2	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0
				14. CENTRAL SYMPTOMS	1	1	1	1	2	2	2	1	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	2	2	2	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	1
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	0	0	0	1	1	1	1	1	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0
				22. Total score				37	37	42	42	22	19	14	14	8	8	5	5	5
2	2	Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	3	2	2	2	2	2	2	2	2	2	2		
				02. GUILT	3	3	3	3	2	2	2	2	2	2	2	2	2	2	1	
				03. SUICIDE	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2	1
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				06. INSOMNIA LATE	2	2	2	2	1	1	2	2	2	2	2	2	2	2	2	1
				07. WORK AND ACTIVITIES	4	4	3	3	3	3	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	3	3	2	2	2	2	0	0	1	1	2	2	2	2	2	0
				09. AGITATION	3	3	2	2	2	2	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	2	2	3	3	2	2	2	2	2	2	2	2	2	1
				11. ANXIETY SOMATIC	0	0	0	0	2	2	1	1	1	1	1	1	1	1	1	0
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	1	2	2	2	2	2	2	2	1
				14. CENTRAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score				36	34	33	33	22	25	24	18	12	12	12	12	12
3	3	Imipramine	Male	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	1		
				02. GUILT	1	1	1	1	2	2	1	1	1	1	1	1	1	1	1	
				03. SUICIDE	2	2	1	1	0	0	1	1	1	1	1	1	1	1	0	
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
1	3	Imipramine	Male	05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1				
				06. INSOMNIA LATE	1	1	1	1	1	1	1					
				07. WORK AND ACTIVITIES	2	2	2	2	1	1	0					
				08. RETARDATION	2	2	1	2	1	2	2					
				09. AGITATION	0	2	1	0	0	0	1					
				10. ANXIETY PSYCHIC	2	2	2	2	2	1	0					
				11. ANXIETY SOMATIC	2	3	1	2	2	0	1					
				12. SOMATIC GASTROINTESTINAL	0	1	2	2	1	1	0					
				13. SOMATIC GENERAL	2	1	2	2	1	1	1					
				14. GENITAL SYMPTOMS	2	2	2	2	2	1	1					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	1	1	2	1	0	0	1					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	0	0	0	0	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0	0					
				22. Total score	22	23	23	21	17	14	13	9				
				4		Placebo	Male	01. DEPRESSED MOOD	3	3	2	0	0	0	0	0
								02. GUILT	3	3	2	0	0	0	0	
								03. SUICIDE	2	2	0	0	0	0	0	
								04. INSOMNIA EARLY	2	2	2	0	0	0	0	
05. INSOMNIA MIDDLE	2	2	1					2	2	1	1					
06. INSOMNIA LATE	1	1	0					0	0	0	0					
07. WORK AND ACTIVITIES	2	2	2					2	1	1	1					
08. RETARDATION	3	3	2					1	1	0	0					
09. AGITATION	1	1	2					1	1	0	0					
10. ANXIETY PSYCHIC	2	2	0					2	2	2	1					
11. ANXIETY SOMATIC	1	1	1					1	1	1	0					
12. SOMATIC GASTROINTESTINAL	2	2	1					1	0	0	0					
13. SOMATIC GENERAL	2	2	1					1	1	1	1					
14. GENITAL SYMPTOMS	1	1	0					0	0	0	0					
15. HYPOCHONDRIASIS	0	0	0					0	0	0	0					
16. LOSS OF WEIGHT	2	2	2					0	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	0	0	0					1	1	0	0					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	29	29	19					12	10	6	5	4				
5		Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2				
				02. GUILT	2	2	2	2	2	2	2					
				03. SUICIDE	1	1	1	1	1	1	1					
				04. INSOMNIA EARLY	2	2	1	1	1	1	1					
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2					
				06. INSOMNIA LATE	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	2	2	3	3	3	3	3					
				08. RETARDATION	2	2	1	1	1	1	1					

1095

9550082

3

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
1	5	Reboxetine	Female	09. AGITATION	2	2	2	2	2	2	2	2				
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2					
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2					
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2					
				13. SOMATIC GENERAL	2	2	2	2	2	2	2					
				14. GENITAL SYMPTOMS	1	1	2	2	2	2	2					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	2	2	2	2	2	2	2					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	2	2	2	2	2	2	2					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	31	31	25	24	25	25	25					
				6	6	Placebo	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2
								02. GUILT	2	2	1	1	1	1	1	
								03. SUICIDE	0	0	1	2	2	2	2	
								04. INSOMNIA EARLY	2	2	2	2	2	2	2	
								05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	
								06. INSOMNIA LATE	2	2	2	2	2	2	2	
								07. WORK AND ACTIVITIES	3	3	2	2	2	2	2	
								08. RETARDATION	2	2	0	0	0	0	0	
09. AGITATION	2	2	0					0	0	0	0					
10. ANXIETY PSYCHIC	2	2	2					2	2	2	2					
11. ANXIETY SOMATIC	2	2	2					2	2	2	2					
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	0	0					
13. SOMATIC GENERAL	2	2	2					2	2	2	2					
14. GENITAL SYMPTOMS	2	2	2					2	2	2	2					
15. HYPOCHONDRIASIS	2	2	2					2	2	2	2					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	1	1	0					0	0	0	0					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	1	1	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	1	1	0					0	0	0	0					
22. Total score	31	31	21					20	23	13	20					
7	7	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	2	1	0	0				
				02. GUILT	2	2	0	1	0	0	0					
				03. SUICIDE	2	2	1	0	0	0	0					
				04. INSOMNIA EARLY	2	2	2	1	0	1	0					
				05. INSOMNIA MIDDLE	2	2	2	1	0	0	0					
				06. INSOMNIA LATE	2	2	2	1	1	0	0					
				07. WORK AND ACTIVITIES	2	2	2	2	1	0	0					
				08. RETARDATION	2	2	2	2	1	0	0					
				09. AGITATION	2	2	2	2	1	0	0					
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1					
				11. ANXIETY SOMATIC	2	2	2	2	1	1	1					
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	1	1	1					

1096

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4

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
1	7	Reboxetine	Female	13.SOMATIC GENERAL	2	2	2	1	1	0	0	0				
				14.GENITAL SYMPTOMS	2	2	1	1	0	0	0	0				
				15.HYPPOCHONDRIASIS	2	2	0	0	0	0	0	0	0			
				16.LOSS OF WEIGHT	1	1	0	0	0	0	0	0	0			
				17.INSIGHT	0	0	0	0	0	0	0	0	0			
				18.DIURNAL VARIATION	1	1	1	0	1	0	0	0	0			
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0			
				20.PARANOID	0	0	0	0	0	0	0	0	0			
				21.OBSESSIONAL/COMPULSIVE	0	0	1	0	0	0	0	0	0			
				22.Total score	33	33	25	20	11	5	2	2				
				8	6	Placebo	Male	01.DEPRESSED MOOD	2	2	2	2	1	1	1	1
								02.GUILT	2	2	1	1	1	1	1	
								03.SUICIDE	0	0	1	0	0	0	0	
								04.INSOMNIA EARLY	2	2	2	1	2	1	1	
								05.INSOMNIA MIDDLE	2	2	2	1	1	1	1	
								06.INSOMNIA LATE	2	2	2	1	1	2	2	
								07.WORK AND ACTIVITIES	2	2	1	1	1	1	1	
								08.RETARDATION	1	1	2	0	1	0	0	
								09.AGITATION	1	1	1	2	1	1	1	
								10.ANXIETY PSYCHIC	2	2	2	1	2	1	1	
								11.ANXIETY SOMATIC	2	2	1	0	1	1	1	
								12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	1	1	
13.SOMATIC GENERAL	1	1	1					0	1	0	0					
14.GENITAL SYMPTOMS	0	0	0					0	0	0	0					
15.HYPPOCHONDRIASIS	1	1	0					0	0	0	0					
16.LOSS OF WEIGHT	1	1	0					0	0	0	0					
17.INSIGHT	0	0	0					0	0	0	0					
18.DIURNAL VARIATION	2	2	1					0	0	0	0					
19.DEPERSONALIZATION	0	0	0					0	0	0	0					
20.PARANOID	0	0	0					0	0	0	0					
21.OBSESSIONAL/COMPULSIVE	1	1	1					1	1	1	1					
22.Total score	27	27	20					14	14	12	9	5				
9	9	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	3	2	2	1				
				02.GUILT	2	2	2	2	2	2	1					
				03.SUICIDE	2	2	2	2	3	2	1					
				04.INSOMNIA EARLY	2	2	2	2	2	1	1					
				05.INSOMNIA MIDDLE	2	2	2	2	2	1	1					
				06.INSOMNIA LATE	2	2	2	2	2	1	1					
				07.WORK AND ACTIVITIES	3	3	2	3	3	2	1					
				08.RETARDATION	2	2	2	2	2	1	1					
				09.AGITATION	3	3	2	2	3	1	1					
				10.ANXIETY PSYCHIC	2	2	2	2	3	1	1					
				11.ANXIETY SOMATIC	2	2	2	2	2	1	1					
				12.SOMATIC GASTROINTESTINAL	1	1	1	2	1	1	0					
				13.SOMATIC GENERAL	2	2	2	1	2	1	1					
				14.GENITAL SYMPTOMS	2	2	2	2	2	1	1					
				15.HYPPOCHONDRIASIS	0	0	0	1	2	2	1					
				16.LOSS OF WEIGHT	0	0	0	1	2	1	0					

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5

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
1	9	Reboxetine	Female	17. INSIGHT	1	1	0	0	1	0	0	0				
				18. DIURNAL VARIATION	2	2	2	0	2	1	1					
				19. DEPERSONALIZATION	3	3	2	0	0	0	0					
				20. PARANOID	0	0	0	0	1	0	0					
				21. OBSESSIONAL/COMPULSIVE	2	2	2	0	0	1	1					
				22. Total score	39	39	33	30	36	21	19	11				
				10		Placebo	Male	01. DEPRESSED MOOD	2	2	2	2	2	2	1	2
								02. GUILT	2	2	2	1	1	2	1	
								03. SUICIDE	2	2	1	1	0	0	1	
								04. INSOMNIA EARLY	2	2	2	1	1	0	0	
								05. INSOMNIA MIDDLE	2	2	1	0	0	0	0	
								06. INSOMNIA LATE	2	2	1	0	0	0	0	
								07. WORK AND ACTIVITIES	2	2	2	1	2	1	2	
08. RETARDATION	2	2	2					1	1	1	1					
09. AGITATION	1	1	1					1	0	1	0					
10. ANXIETY PSYCHIC	3	2	0					0	1	2	1					
11. ANXIETY SOMATIC	2	3	0					0	1	1	1					
12. SOMATIC GASTROINTESTINAL	2	1	0					0	0	0	0					
13. SOMATIC GENERAL	1	2	2					1	1	1	1					
14. GENERAL SYMPTOMS	0	0	1					0	0	0	0					
15. HYPOCHONDRIASIS	1	1	2					1	2	2	2					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	1	1	1					0	0	0	0					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	1	1	0	0	1	0	1									
22. Total score	28	28	20	12	13	13	12	11								
11		Imipramine	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	1	2				
				02. GUILT	1	1	1	1	1	1	1					
				03. SUICIDE	2	2	2	2	2	2	2					
				04. INSOMNIA EARLY	2	2	2	2	2	2	2					
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2					
				06. INSOMNIA LATE	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3					
				08. RETARDATION	2	2	2	2	2	2	2					
				09. AGITATION	0	0	0	0	0	0	0					
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2					
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2					
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2					
				13. SOMATIC GENERAL	2	2	2	2	2	2	2					
14. GENERAL SYMPTOMS	0	0	0	0	0	0	0									
15. HYPOCHONDRIASIS	0	0	0	0	0	0	0									
16. LOSS OF WEIGHT	1	1	1	1	1	1	1									
17. INSIGHT	0	0	0	0	0	0	0									
18. DIURNAL VARIATION	1	1	1	1	1	1	1									
19. DEPERSONALIZATION	0	0	0	0	0	0	0									
20. PARANOID	0	0	0	0	0	0	0									
21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1									
22. Total score	28	28	28	28	28	28	28	28								

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6

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
1	11	Imipramine	Female	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0						
				22. Total score	26	26												
				12	Imipramine	Female	01. DEPRESSED MOOD	2	2	2	1	1	1	1	0	0		
							02. GUILT	2	2	2	1	0	1	0	0	0	0	
							03. SUICIDE	2	2	1	0	0	1	0	0	0	0	
							04. INSOMNIA EARLY	0	0	0	0	0	1	0	0	0	0	
							05. INSOMNIA MIDDLE	0	0	0	0	0	1	1	1	1	1	
							06. INSOMNIA LATE	0	0	0	0	1	0	0	1	0	0	
							07. WORK AND ACTIVITIES	3	3	2	1	1	0	1	1	0	1	1
							08. RETARDATION	2	2	1	0	1	1	0	1	0	0	0
							09. AGITATION	2	2	1	1	1	1	1	1	0	1	1
							10. ANXIETY PSYCHIC	2	2	2	2	2	1	1	1	1	1	1
							11. ANXIETY SOMATIC	1	1	2	2	1	1	1	1	1	1	1
							12. SOMATIC GASTROINTESTINAL	0	0	1	0	0	0	0	0	0	0	0
							13. SOMATIC GENERAL	2	2	2	2	2	2	1	1	1	1	1
							14. GENITAL SYMPTOMS	2	2	2	2	2	2	0	2	1	1	1
							15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0
							16. LOSS OF WEIGHT	1	1	0	0	0	0	0	0	0	0	0
							17. INSTINCT	0	0	0	0	0	0	0	0	0	0	0
							18. DIURNAL VARIATION	1	1	1	2	0	0	0	0	0	0	0
							19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0
							20. PARANOID	0	0	0	0	0	0	0	0	0	0	0
							21. OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0	0	0	0	0
22. Total score	23	23	20				12	8	11	6	5							
412	Reboxetine	Male	01. DEPRESSED MOOD				3	3	2	2	2	2	2	1	1			
			02. GUILT	2	2	2	2	2	2	1	0	0	0					
			03. SUICIDE	2	2	1	1	1	1	0	0	0	0					
			04. INSOMNIA EARLY	2	2	1	2	1	0	1	0	0	0					
			05. INSOMNIA MIDDLE	1	1	1	2	1	1	1	1	0	0					
			06. INSOMNIA LATE	1	1	1	2	1	1	1	1	0	0					
			07. WORK AND ACTIVITIES	3	3	2	2	2	3	3	3	1	1					
			08. RETARDATION	2	2	1	1	1	1	0	0	0	0					
			09. AGITATION	0	0	1	1	1	1	0	0	0	0					
			10. ANXIETY PSYCHIC	3	3	1	2	2	1	0	1	0	1					
			11. ANXIETY SOMATIC	2	2	0	0	2	1	1	1	0	0					
			12. SOMATIC GASTROINTESTINAL	1	1	2	2	2	1	0	1	1	1					
			13. SOMATIC GENERAL	1	1	2	2	2	2	1	1	0	0					
			14. GENITAL SYMPTOMS	1	1	2	1	0	0	0	0	0	0					
			15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0					
			16. LOSS OF WEIGHT	1	1	1	1	0	0	0	0	0	0					
			17. INSTINCT	0	0	0	0	0	0	0	0	0	0					
			18. DIURNAL VARIATION	1	1	0	0	0	0	0	0	0	0					
			19. DEPERSONALIZATION	1	1	0	0	0	0	0	0	0	0					
			20. PARANOID	0	0	0	0	0	0	0	0	0	0					
			21. OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0	0	0	0	0					
			22. Total score	29	29	21	21	18	15	6	4							

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
1	413	Placebo	Male	01. DEPRESSED MOOD	2	3	3		1		2	2		
				02. GUILT	2	2	2							
				03. SUICIDE	2	2	1							
				04. INSOMNIA EARLY	2	2	2							
				05. INSOMNIA MIDDLE	1	2	0							
				06. INSOMNIA LATE	0	2	0							
				07. WORK AND ACTIVITIES	2	2	3							
				08. RETARDATION	0	2	1							
				09. AGITATION	2	2	2							
				10. ANXIETY PSYCHIC	2	1	2							
				11. ANXIETY SOMATIC	1	1	2							
				12. SOMATIC GASTROINTESTINAL	1	1	2							
				13. SOMATIC GENERAL	1	1	0							
				14. GENITAL SYMPTOMS	1	1	1							
				15. HYPOCHONDRIASIS	2	2	0							
				16. LOSS OF HEIGHT	0	0	0							
				17. INSIGHT	0	0	0							
				18. DIURNAL VARIATION	1	1	1							
				19. DEPERSONALIZATION	0	0	0							
				20. PARANOID	0	0	0							
				21. OBSESSIONAL/COMPULSIVE	1	1	1							
				22. Total score				23	28	22		14		
414	Imipramine	Female	01. DEPRESSED MOOD	2	2	2								
			02. GUILT	2	0	0								
			03. SUICIDE	1	0	1								
			04. INSOMNIA EARLY	2	2	2								
			05. INSOMNIA MIDDLE	2	2	2								
			06. INSOMNIA LATE	2	2	2								
			07. WORK AND ACTIVITIES	3	3	3								
			08. RETARDATION	2	2	2								
			09. AGITATION	3	1	0								
			10. ANXIETY PSYCHIC	2	1	2								
			11. ANXIETY SOMATIC	2	2	2								
			12. SOMATIC GASTROINTESTINAL	1	1	1								
			13. SOMATIC GENERAL	2	2	2								
			14. GENITAL SYMPTOMS	1	2	1								
			15. HYPOCHONDRIASIS	0	0	0								
			16. LOSS OF HEIGHT	0	2	0								
			17. INSIGHT	0	0	0								
			18. DIURNAL VARIATION	2	0	0								
			19. DEPERSONALIZATION	0	0	0								
			20. PARANOID	1	1	0								
			21. OBSESSIONAL/COMPULSIVE	0	0	0								
			22. Total score				30	25	22		25			
415	Imipramine	Male	01. DEPRESSED MOOD	2	2	1			1		1	0		
			02. GUILT	1	1	1								
			03. SUICIDE	1	1	1								
			04. INSOMNIA EARLY	2	2	2								

1100

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8

PHARMACIA CNS RD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	7	14	21	28	35	Day 42				
1	415	Imipramine	Male	05. INSOMNIA MIDDLE	2	2	2	1	1	1	2	2				
				06. INSOMNIA LATE	1	1	1	1	1	0	1					
				07. WORK AND ACTIVITIES	2	2	2	1	1	0	0					
				08. RETARDATION	1	1	0	1	1	0	0					
				09. AGITATION	2	2	2	1	0	0	1					
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1					
				11. ANXIETY SOMATIC	2	2	2	2	2	1	1					
				12. SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0					
				13. SOMATIC GENERAL	1	1	1	0	0	1	1					
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	0	0	1	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	0	0	0	0	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0					
				22. Total score	22	22	22	15	12	8	7					
				1101	416	Reboxetine	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2
								02. GUILT	2	2	1	1	1	1	1	
								03. SUICIDE	2	2	2	2	2	2	2	
								04. INSOMNIA EARLY	1	1	2	2	2	2	2	
05. INSOMNIA MIDDLE	2	2	2					2	2	2	2					
06. INSOMNIA LATE	2	2	2					2	2	2	2					
07. WORK AND ACTIVITIES	0	0	0					1	0	0	0					
08. RETARDATION	2	2	2					2	2	2	2					
09. AGITATION	2	2	2					2	2	2	2					
10. ANXIETY PSYCHIC	3	2	2					2	2	2	2					
11. ANXIETY SOMATIC	3	2	3					2	2	2	2					
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1					
13. SOMATIC GENERAL	1	1	1					1	1	1	1					
14. GENITAL SYMPTOMS	1	1	1					1	1	1	1					
15. HYPOCHONDRIASIS	3	2	2					2	2	2	2					
16. LOSS OF WEIGHT	1	1	1					1	1	1	1					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	1	1	1					1	1	1	1					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	29	26	26					25	25	25	25					
421	421	Imipramine	Male	01. DEPRESSED MOOD	2	2	2	1	1	1	1	1				
				02. GUILT	1	1	1	1	0	0	0					
				03. SUICIDE	3	3	3	1	0	0	0					
				04. INSOMNIA EARLY	1	1	1	1	1	0	0					
				05. INSOMNIA MIDDLE	2	2	2	1	0	1	1					
				06. INSOMNIA LATE	2	2	1	1	1	0	0					
				07. WORK AND ACTIVITIES	3	3	3	2	1	1	1					
				08. RETARDATION	2	2	2	1	1	1	1					

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9

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
1	421	Imipramine	Male	09. ACITATION	0	0	0	0	1	0	0	0				
				10. ANXIETY PSYCHIC	2	2	2	1	0	1	1					
				11. ANXIETY SOMATIC	2	1	1	1	0	1	0					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0					
				13. SOMATIC GENERAL	1	1	1	1	0	2	2					
				14. GENITAL SYMPTOMS	2	2	1	1	0	1	0					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	0	0	1	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	1	1	0	0	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	25	25	22	15	10	5	9	6				
				422	422	Imipramine	Male	01. DEPRESSED MOOD	2	2	2	2	1	1	1	0
								02. GUILT	1	1	1	1	0	0	0	
								03. SUICIDE	1	1	0	1	0	1	0	
								04. INSOMNIA EARLY	2	2	1	0	1	0	0	
								05. INSOMNIA MIDDLE	2	2	0	1	1	1	1	
								06. INSOMNIA LATE	1	1	0	0	0	0	0	
								07. WORK AND ACTIVITIES	3	3	2	1	1	1	0	
								08. RETARDATION	0	0	0	0	1	0	0	
09. AGITATION	2	2	0					0	0	1	1					
10. ANXIETY PSYCHIC	2	2	1					1	1	1	0					
11. ANXIETY SOMATIC	2	2	1					1	1	1	0					
12. SOMATIC GASTROINTESTINAL	1	1	1					0	1	0	1					
13. SOMATIC GENERAL	1	1	1					0	1	0	0					
14. GENITAL SYMPTOMS	0	0	1					2	1	0	0					
15. HYPOCHONDRIASIS	1	1	1					1	0	0	0					
16. LOSS OF WEIGHT	1	1	1					1	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	1	1	1					1	0	0	0					
19. DEPERSONALIZATION	0	0	1					0	0	0	0					
20. PARANOID	1	1	1					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	24	24	19					12	9	8	4	5				
2/1	49	Placebo	Female	01. DEPRESSED MOOD	4	4	3	1	0	0	0	0				
				02. GUILT	1	1	1	0	0	0	0					
				03. SUICIDE	4	1	1	0	0	0	0					
				04. INSOMNIA EARLY	0	0	0	0	0	0	0					
				05. INSOMNIA MIDDLE	0	2	2	2	2	2	1					
				06. INSOMNIA LATE	0	1	1	1	1	0	0					
				07. WORK AND ACTIVITIES	3	3	1	0	0	0	0					
				08. RETARDATION	3	3	2	0	0	0	0					
				09. AGITATION	0	0	0	0	0	0	0					
				10. ANXIETY PSYCHIC	3	3	3	1	0	0	0					
				11. ANXIETY SOMATIC	3	3	3	1	0	0	0					
				12. SOMATIC GASTROINTESTINAL	1	1	2	1	1	1	0					

1102

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10

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
2/1	49	Placebo	Female	13. SOMATIC GENERAL	2	2	1	0	0	0	0	0				
				14. CERITAL SYMPTOMS	0	0	0	0	0	0	0					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	0	0	1	0	0	0	0					
				17. INSIGHT	1	0	0	0	0	0	0					
				18. DIURNAL VARIATION	0	0	0	0	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	23	22	22	9	5	3	2	1				
				50		Reboxetine	Female	01. DEPRESSED MOOD	3	3	1	0	0	0	0	0
								02. GUILT	2	2	1	1	0	0	0	
								03. SUICIDE	0	0	0	0	0	0	0	
								04. INSOMNIA EARLY	2	2	2	2	2	2	2	
								05. INSOMNIA MIDDLE	2	2	2	2	1	0	0	
								06. INSOMNIA LATE	0	0	0	0	0	0	0	
								07. WORK AND ACTIVITIES	4	3	1	0	0	0	0	
								08. RETARDATION	1	1	1	0	0	0	0	
								09. AGITATION	1	1	0	0	0	0	0	
								10. ANXIETY PSYCHIC	3	3	1	1	2	1	1	
								11. ANXIETY SOMATIC	2	2	3	3	3	2	1	
								12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	1	
								13. SOMATIC GENERAL	2	1	0	0	0	0	0	
14. CERITAL SYMPTOMS	0	0	0					0	0	0	0					
15. HYPOCHONDRIASIS	0	0	0					0	0	0	0					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	1	1	1					1	1	1	2					
18. DIURNAL VARIATION	1	1	0					0	0	0	0					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	25	22	14					11	9	8	7					
51		Imipramine	Female					01. DEPRESSED MOOD	4	3	2	1	1	0	0	0
				02. GUILT	3	3	1	1	1	0	0					
				03. SUICIDE	2	2	1	0	0	0	0					
				04. INSOMNIA EARLY	0	0	2	2	2	2	2					
				05. INSOMNIA MIDDLE	2	2	2	0	0	0	0					
				06. INSOMNIA LATE	2	2	1	0	0	0	0					
				07. WORK AND ACTIVITIES	3	3	3	2	0	0	0					
				08. RETARDATION	2	1	1	0	0	0	0					
				09. AGITATION	2	2	1	1	0	0	0					
				10. ANXIETY PSYCHIC	3	3	3	2	1	2	2					
				11. ANXIETY SOMATIC	2	2	3	3	1	2	2					
				12. SOMATIC GASTROINTESTINAL	2	2	0	2	1	0	0					
				13. SOMATIC GENERAL	2	2	2	2	1	0	0					
				14. CERITAL SYMPTOMS	2	2	2	2	2	2	2					
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					

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11

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PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/1	51	Imipramine	Female	17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	0 0 0 0 0 32	0 0 0 0 0 30	0 0 0 0 0 27	0 0 0 0 0 20	0 0 0 0 0 12	0 0 0 0 0 11	0 0 0 0 0 13
2/2	43	Imipramine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	2 2 2 2 2 0 3 2 2 1 2 0 1 0 2 2 1 1 0 0 24	2 2 2 2 2 0 3 2 2 1 2 0 1 0 2 2 1 1 0 0 25	0 0 0 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 15	0 4	0 4	0 4	
44		Imipramine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID	3 2 0 2 2 1 0 2 2 2 2 0 0 0 0 0 0 0 0 0 24	3 2 0 2 2 1 0 2 2 2 2 0 0 0 0 0 0 0 0 0 25	1 1 0 1 1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 15	1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 4	1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 4	0 4	

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12

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PHARMACIA CNS RED.
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
2/2	44	Imipramine	Female	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	22	25	14	14	10	16	7						
45		Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	3	3	2	1	3						
				02. GUILT	3	3	1	2	1	1	1	1						
				03. SUICIDE	2	2	1	0	0	0	0	0						
				04. INSOMNIA EARLY	2	1	0	0	0	0	0	1						
				05. INSOMNIA MIDDLE	0	0	1	1	1	0	0	0						
				06. INSOMNIA LATE	1	1	1	1	1	0	0	1						
				07. WORK AND ACTIVITIES	2	1	2	0	2	0	0	0						
				08. RETARDATION	0	1	1	0	0	0	0	1						
				09. AGITATION	0	2	0	1	1	2	1	0						
				10. ANXIETY PSYCHIC	2	1	1	1	1	2	2	1						
				11. ANXIETY SOMATIC	1	1	1	1	1	0	1	1						
				12. SOMATIC GASTROINTESTINAL	1	0	0	0	0	0	0	0						
				13. SOMATIC GENERAL	2	2	1	0	0	0	0	1						
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0						
				15. HYPOCHONDRIASIS	3	2	2	1	2	2	2	2						
				16. LOSS OF HEIGHT	0	0	2	0	0	0	0	0						
				17. INSIGHT	0	0	0	0	0	0	0	0						
				18. DIURNAL VARIATION	1	1	0	0	2	0	0	0						
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0						
				20. PARANOID	0	1	0	1	1	1	1	1						
				21. OBSESSIONAL/COMPULSIVE	2	1	0	0	0	0	0	1						
				22. Total score	25	23	17	12	14	11	13	13						
46		Placebo	Female	01. DEPRESSED MOOD	3	2	3	3	1	0								
				02. GUILT	1	1	1	1	1	0								
				03. SUICIDE	2	2	0	0	0	0								
				04. INSOMNIA EARLY	2	2	0	0	1	0								
				05. INSOMNIA MIDDLE	2	2	0	0	0	0								
				06. INSOMNIA LATE	1	1	0	0	0	0								
				07. WORK AND ACTIVITIES	3	2	1	0	1	1								
				08. RETARDATION	0	0	1	0	1	0								
				09. AGITATION	2	2	2	0	1	0								
				10. ANXIETY PSYCHIC	2	2	0	0	1	0								
				11. ANXIETY SOMATIC	2	2	0	0	0	0								
				12. SOMATIC GASTROINTESTINAL	1	0	0	0	0	0								
				13. SOMATIC GENERAL	2	2	1	0	2	0								
				14. GENITAL SYMPTOMS	0	0	1	2	2	1								
				15. HYPOCHONDRIASIS	0	0	0	0	0	0								
				16. LOSS OF HEIGHT	0	0	2	0	2	1								
				17. INSIGHT	0	0	0	0	0	0								
				18. DIURNAL VARIATION	0	2	0	0	0	0								
				19. DEPERSONALIZATION	0	0	0	0	0	0								
				20. PARANOID	1	1	0	0	1	1								
				21. OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0								
				22. Total score	25	25	9	12	12	4								

1105

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13

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient	Treatment	Sex	HAMILTON DEPRESSION RATING SCALE													
				Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35
2/2	47	Placebo	Female	4	3	3	2	2	2	3	3	3	2	2	3	3	2
				2	1	1	1	1	1	1	1	1	1	1	1	1	0
				0	2	2	2	2	2	2	2	2	2	2	2	2	0
				1	2	2	2	2	2	2	2	2	2	2	2	2	0
				1	1	1	1	1	1	1	1	1	1	1	1	1	0
				4	3	4	3	4	3	4	3	4	3	4	3	4	2
				1	2	1	0	0	1	1	1	1	1	1	1	1	1
				3	1	1	2	1	1	1	1	1	1	1	1	1	2
				2	3	2	2	2	2	2	2	2	2	2	2	2	1
				1	2	1	1	1	1	1	1	1	1	1	1	1	1
				0	2	2	2	2	2	2	2	2	2	2	2	2	1
				2	2	2	2	2	2	2	2	2	2	2	2	2	2
				0	2	1	0	0	0	0	0	0	0	0	0	0	0
				0	1	1	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	1	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0
				23	31	27	16	13	21	20	16	20	16	20	16	20	16
				4	4	3	3	1	2	0	1	1	1	1	1	1	1
				2	2	1	0	0	0	0	0	0	0	0	0	0	0
				0	1	0	0	0	0	0	0	0	0	0	0	0	0
				2	2	0	0	0	0	0	0	0	0	0	0	0	0
				2	2	0	0	0	0	0	0	0	0	0	0	0	0
				1	1	2	1	2	1	0	2	1	1	1	1	1	1
				4	4	4	4	4	4	2	0	0	0	0	0	0	0
				2	2	2	2	2	2	1	1	1	1	1	1	1	1
				1	3	1	3	1	3	1	1	1	1	1	1	1	1
				0	0	1	0	0	0	0	0	0	0	0	0	0	0
				2	1	1	1	1	1	1	1	1	1	1	1	1	1
				0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	2	0	0	0	0	0	0	0	0	0	0	0
				1	1	0	0	0	0	0	0	0	0	0	0	0	0
				1	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	6	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0
				1	0	0	0	0	0	0	0	0	0	0	0	0	0
				26	28	21	19	10	8	3	8	3	8	3	8	3	8
2/3	36/A	Imipramine	Male	3	3	3	1	1	1	1	1	1	1	1	1	1	1
				1	2	2	0	0	0	0	0	0	0	0	0	0	0
				1	2	2	0	0	0	0	0	0	0	0	0	0	0
				2	2	2	1	1	1	1	1	1	1	1	1	1	1

1106

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14

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/3	36/A	Imipramine	Male		2	1	1	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	1	1	0	0	0	0	0
				06. INSOMNIA LATE	2	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	3	1	1	1	1	1
				08. RETARDATION	1	2	2	0	0	0	0	0
				09. AGITATION	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	1	2	2	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	2	2	0	1	1	1	1
				22. Total score	27	27	27	10	11	10	10	10
				01. DEPRESSED MOOD	5	3	3	3	2	2	2	1
				02. GUILT	1	1	1	1	1	0	0	0
				03. SUICIDE	1	1	1	1	1	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	1	1	1
				07. WORK AND ACTIVITIES	3	3	0	3	2	2	2	1
				08. RETARDATION	2	2	2	1	0	0	0	0
				09. AGITATION	0	0	1	1	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	3	3	3	3	3	1
				11. ANXIETY SOMATIC	2	2	3	3	3	3	3	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	2	2	2	2	2	1
				15. HYPOCHONDRIASIS	0	0	1	1	1	1	1	0
				16. LOSS OF WEIGHT	1	1	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	24	24	26	25	23	21	21	10
				01. DEPRESSED MOOD	2	2	2	2	2	2	1	1
				02. GUILT	2	2	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	3	2	2	2	2	1	1
				08. RETARDATION	3	3	2	2	2	2	1	1

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15

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/3	38	Placebo	Male	09. ACITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	0	0	0	0	0	1	1	1
					3	3	2	2	2	0	0	0
					3	3	2	2	2	2	2	1
					1	1	1	1	2	2	1	1
					1	1	1	1	2	2	1	1
					2	2	2	2	2	2	1	1
					2	2	2	2	1	1	0	0
					0	0	0	0	0	0	0	0
					1	1	1	1	1	1	1	1
					1	1	1	1	0	0	0	0
					1	1	1	1	0	0	0	0
					0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0
					31	32	25	25	21	19	13	14
39		Imipramine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. ACITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3	3	3	2	2	1	1	0
					2	2	2	1	0	0	0	0
					1	2	2	1	0	0	0	0
					2	2	2	1	0	0	0	0
					2	2	1	1	0	0	0	0
					3	3	3	2	1	1	0	0
					3	1	0	0	0	0	0	0
					0	0	0	0	0	0	0	0
					3	3	3	2	2	1	1	1
					2	2	2	2	0	0	1	1
					2	2	2	2	2	1	0	0
					1	1	1	1	1	0	0	0
					1	2	1	1	2	0	0	0
					1	1	1	1	0	0	0	0
					0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0
					32	33	29	20	12	8	5	3
40		Reboxetine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. ACITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL	3	3	2	2	0	0	0	0
					1	1	2	1	1	1	0	0
					0	0	0	0	0	0	0	0
					2	2	2	1	1	2	2	0
					2	2	0	0	0	1	1	0
					1	1	0	0	0	0	0	0
					3	3	4	4	3	1	0	2
					0	0	0	0	0	1	1	1
					0	0	0	0	0	2	0	0
					3	3	3	3	2	1	1	1
					1	1	1	0	0	1	1	0
					2	2	1	0	0	0	0	0

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16

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PHARMACIA CNS RED
 ZERONEXINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
2/3	40	Reboxetine	Female	13. SOMATIC GENERAL	0	0	0	0	0	1	1	0				
				14. GENITAL SYMPTOMS	1	1	0	0	0	0	0	0	0			
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0			
				16. LOSS OF WEIGHT	2	2	0	0	0	0	0	0	0			
				17. INSIGHT	0	0	2	2	1	0	1	1	1	1		
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0		
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0		
				20. PARANOID	1	1	0	0	0	0	0	0	0	0		
				21. OBSESSIONAL/COMPULSIVE	1	1	2	2	2	0	0	1	1	1		
				22. Total score	23	23	19	15	10	14	8	6				
				41	41	Placebo	Male	01. DEPRESSED MOOD	3	3	2	2	3	3	2	2
								02. GUILT	2	2	1	0	0	0	0	0
03. SUICIDE	1	1	0					1	0	0	0	0				
04. INSOMNIA EARLY	0	0	0					0	0	0	0	0				
05. INSOMNIA MIDDLE	1	1	1					1	0	0	0	0				
06. INSOMNIA LATE	1	1	2					2	0	0	0	0				
07. WORK AND ACTIVITIES	4	4	4					4	4	4	4	4				
08. RETARDATION	1	1	2					2	2	2	2	2				
09. AGITATION	2	2	1					2	1	0	2	0				
10. ANXIETY PSYCHIC	2	2	3					2	3	0	0	2				
11. ANXIETY SOMATIC	1	1	1					0	0	0	0	0				
12. SOMATIC GASTROINTESTINAL	0	0	1					1	0	0	0	0				
13. SOMATIC GENERAL	1	1	1	0	0	0	0	0								
14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2								
15. HYPOCHONDRIASIS	2	2	2	0	0	2	2	2								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0								
17. INSIGHT	1	1	1	2	1	1	1	1								
18. DIURNAL VARIATION	1	1	2	1	2	2	2	2								
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0								
20. PARANOID	0	0	0	0	0	0	0	0								
21. OBSESSIONAL/COMPULSIVE	1	1	1	0	1	1	2	1								
22. Total score	26	27	26	22	19	18	18	18								
42	42	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	1	0	0	2				
				02. GUILT	2	2	1	1	0	1	0	0				
				03. SUICIDE	0	0	0	0	0	0	0	0				
				04. INSOMNIA EARLY	2	2	1	2	2	0	1	1				
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1				
				06. INSOMNIA LATE	1	1	0	1	0	1	0	0				
				07. WORK AND ACTIVITIES	3	3	3	2	1	2	2	0				
				08. RETARDATION	3	3	2	2	1	2	1	2				
				09. AGITATION	2	0	1	0	0	0	0	0				
				10. ANXIETY PSYCHIC	3	2	2	2	2	1	0	1				
				11. ANXIETY SOMATIC	2	2	1	1	1	0	1	1				
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	1	0	1				
13. SOMATIC GENERAL	2	1	1	2	1	0	1	1								
14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0								
15. HYPOCHONDRIASIS	2	3	2	2	2	2	2	2								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0								

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17

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
2/3	42	Female	17. INSIGHT	1	1	1	1	1	1	1	1	
			18. DIURNAL VARIATION	2	2	0	1	1	0	0	0	0
			19. DEPERSONALIZATION	0	0	0	2	0	0	0	0	0
			20. PARANOID	0	1	1	2	1	1	1	1	1
			21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0
	22. Total score		30	28	20	25	15	15	14	14		
2/4	31	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	2	2	
			02. GUILT	1	1	1	1	1	1	1	1	1
			03. SUICIDE	3	3	3	2	2	2	2	2	2
			04. INSOMNIA EARLY	2	2	2	1	1	1	1	1	1
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1
			06. INSOMNIA LATE	3	3	3	3	3	3	3	2	2
			07. WORK AND ACTIVITIES	4	4	2	2	2	2	2	2	2
			08. RETARDATION	3	3	3	3	3	3	3	3	3
			09. AGITATION	2	2	2	2	2	2	2	2	2
			10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3
			11. ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3
			12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2
			13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1
			14. GENITAL SYMPTOMS	1	1	2	2	2	2	2	2	2
			15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2
			16. LOSS OF WEIGHT	3	3	3	3	3	3	3	3	3
			17. INSIGHT	0	0	0	0	0	0	0	0	0
			18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2
			19. DEPERSONALIZATION	3	3	3	3	3	3	3	3	3
			20. PARANOID	2	2	2	2	2	2	2	2	2
21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1			
	22. Total score		44	45	44	39	36	36	29	29		
32	Male	01. DEPRESSED MOOD	4	4	4	4	3	3	3	3		
		02. GUILT	3	3	3	3	3	3	3	3	3	
		03. SUICIDE	2	2	2	2	2	2	2	2	2	
		04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	
		05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	
		06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	
		07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	
		08. RETARDATION	3	3	3	3	3	3	3	3	3	
		09. AGITATION	3	3	3	3	3	3	3	3	3	
		10. ANXIETY PSYCHIC	4	4	4	4	4	4	4	4	4	
		11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	
		12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	
		13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	
		14. GENITAL SYMPTOMS	4	4	4	4	4	4	4	4	4	
		15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	
		16. LOSS OF WEIGHT	4	4	4	4	4	4	4	4	4	
		17. INSIGHT	1	1	1	1	1	1	1	1	1	
		18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	
		19. DEPERSONALIZATION	3	3	3	3	3	3	3	3	3	
		20. PARANOID	2	2	2	2	2	2	2	2	2	

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18

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/4	32	Reboxetine	Male	21. OBSESSIONAL/COMPULSIVE 22. total score	2 48	2 46	2 43	2 43	2 33	1 19	1 18	1 15
	33	Imipramine	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. total score	3 4 1 2 2 2 1 1 2 3 0 0 0 0 0 0 0 0 2 2 2 1 1 29	4 4 1 2 2 2 1 1 2 3 0 0 0 0 0 0 0 0 2 2 2 1 1 29	3 4 1 2 2 2 1 1 2 3 0 0 0 0 0 0 0 0 2 2 2 1 1 29	3 4 1 2 2 2 1 1 2 3 0 0 0 0 0 0 0 0 2 2 2 1 1 29	2 2 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 20	2 2 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 12	1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 7	
	34	Placebo	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. total score	4 4 2 2 2 1 3 3 4 4 2 2 0 0 0 0 0 0 2 2 2 1 1 54	4 4 2 2 2 1 3 3 4 4 2 2 0 0 0 0 0 0 2 2 2 1 1 53	3 3 2 2 2 1 3 3 4 4 2 2 0 0 0 0 0 0 2 2 2 1 1 51	3 3 2 2 2 1 3 3 4 4 2 2 0 0 0 0 0 0 2 2 2 1 1 39	2 2 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 24	2 2 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 19	0 0 1 1 1 1 1 1 1 1 1 1 0 0 0 0 0 0 1 1 1 1 1 16	

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19

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/4	35	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	3	2	1	1	1
				02. GUILT	3	3	3	2	2	1	1	1
				03. SUICIDE	3	3	3	2	2	1	1	0
				04. INSOMNIA EARLY	2	2	2	2	2	1	0	0
				05. INSOMNIA MIDDLE	2	2	2	1	1	1	1	0
				06. INSOMNIA LATE	2	2	2	2	2	1	1	0
				07. WORK AND ACTIVITIES	3	3	3	3	2	1	1	1
				08. RETARDATION	3	3	3	3	2	2	1	1
				09. AGITATION	3	3	3	3	2	1	1	0
				10. ANXIETY PSYCHIC	4	4	4	3	2	1	1	1
				11. ANXIETY SOMATIC	3	3	2	2	2	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	0	0	0	0
				13. SOMATIC GENERAL	2	2	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	4	4	3	3	2	2	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	2	2	1	1	1	1
				18. DIURNAL VARIATION	1	2	2	2	1	1	1	0
				19. DEPERSONALIZATION	3	3	3	2	1	1	1	1
				20. PARANOID	2	2	2	1	1	1	1	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1
				22. Total score	48	49	45	40	29	20	14	11
				01. DEPRESSED MOOD	4	4	4	3	2	1	0	0
				02. GUILT	3	3	3	3	2	1	1	0
				03. SUICIDE	2	2	3	1	1	1	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	0	0	0
				05. INSOMNIA MIDDLE	2	2	2	2	2	0	0	0
				06. INSOMNIA LATE	2	2	2	2	2	0	0	0
				07. WORK AND ACTIVITIES	4	4	4	3	2	2	1	1
				08. RETARDATION	3	3	3	3	2	2	1	1
				09. AGITATION	4	4	4	3	2	1	1	0
				10. ANXIETY PSYCHIC	4	4	4	3	2	1	1	1
				11. ANXIETY SOMATIC	3	3	3	3	2	1	1	1
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	3	3	3	3	2	1	0	0
				15. HYPOCHONDRIASIS	3	3	3	3	1	1	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	2	2	1	1	1	1
				18. DIURNAL VARIATION	2	2	2	2	2	1	1	1
				19. DEPERSONALIZATION	3	3	3	3	2	1	1	0
				20. PARANOID	3	3	3	3	2	1	1	0
				21. OBSESSIONAL/COMPULSIVE	2	2	2	2	1	1	0	0
				22. Total score	51	51	52	46	32	18	9	6
2/5	73	Placebo	Male	01. DEPRESSED MOOD	2	2	1	1	1	3	3	3
				02. GUILT	2	2	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	1	1	2
				04. INSOMNIA EARLY	1	1	1	1	1	2	1	2

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42									
2/5	73	Placebo	Male	05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1								
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1						
				07. WORK AND ACTIVITIES	4	4	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	3	3				
				08. RETARDATION	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2				
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2				
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				15. HYPOCHONDRIASIS	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3			
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				22. Total score	24	24	19	18	11	22	20	20	20	20	20	20	20	20	20	20	20	20	20	26	26			
				7/4	74	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0	0		
								02. GUILT	3	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
								03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
								04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
05. INSOMNIA MIDDLE	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
06. INSOMNIA LATE	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
07. WORK AND ACTIVITIES	2	3	2					2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
08. RETARDATION	2	2	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
09. AGITATION	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
10. ANXIETY PSYCHIC	3	3	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
11. ANXIETY SOMATIC	2	2	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
13. SOMATIC GENERAL	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
14. GENITAL SYMPTOMS	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
15. HYPOCHONDRIASIS	3	3	3					3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3			
16. LOSS OF WEIGHT	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
17. INSIGHT	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
18. DIURNAL VARIATION	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
19. DEPERSONALIZATION	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
20. PARANOID	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
22. Total score	26	26	16					12	7	5	4	4	4	4	4	4	4	4	4	4	4	4	4	30	30			
7/5	75	Imipramine	Male	01. DEPRESSED MOOD	3	3	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	0	0					
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				06. INSOMNIA LATE	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3			
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			

1113

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21

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/5	75	Imipramine	Male		3	2	2	1	2	2	0	0
				09. AGITATION	3	2	2	1	2	2	0	0
				10. ANXIETY PSYCHIC	3	2	2	1	2	1	0	0
				11. ANXIETY SOMATIC	1	1	2	1	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	1	1	1	0	0	0	1	0
				15. HYPOCHONDRIASIS	1	2	1	1	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	24	24	19	11	9	6	2	1
				01. DEPRESSED MOOD	3	3	2	1	3	1	1	0
				02. GUILT	0	1	1	0	2	0	1	0
				03. SUICIDE	1	1	1	0	1	0	0	0
				04. INSOMNIA EARLY	2	1	1	0	0	1	0	0
				05. INSOMNIA MIDDLE	1	1	1	0	0	1	0	0
				06. INSOMNIA LATE	1	1	1	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	2	1	3	2	1	1
				08. RETARDATION	0	2	2	0	1	0	0	0
				09. AGITATION	4	2	2	1	0	0	0	0
				10. ANXIETY PSYCHIC	3	2	2	1	2	1	0	0
				11. ANXIETY SOMATIC	3	1	1	0	1	0	0	0
				12. SOMATIC GASTROINTESTINAL	0	0	1	0	0	0	0	1
				13. SOMATIC GENERAL	2	1	1	0	2	0	0	0
				14. GENITAL SYMPTOMS	2	2	2	1	2	2	0	0
				15. HYPOCHONDRIASIS	1	3	2	1	2	0	0	0
				16. LOSS OF WEIGHT	1	0	0	0	0	0	0	0
				17. INSIGHT	0	0	1	0	0	0	0	0
				18. DIURNAL VARIATION	0	1	1	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	29	26	25	11	19	9	5	2
				01. DEPRESSED MOOD	4	3	1	2	1	0	0	0
				02. GUILT	3	3	1	1	1	0	0	0
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	0	1	0	1	0	0	0	0
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	0	1	1	1	1	0	0	0
				07. WORK AND ACTIVITIES	3	3	2	1	1	1	1	0
				08. RETARDATION	3	2	1	1	1	1	0	0
				09. AGITATION	2	2	2	1	0	0	0	0
				10. ANXIETY PSYCHIC	3	2	1	1	1	0	1	1
				11. ANXIETY SOMATIC	2	2	1	1	0	0	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	1	0	0	1	0	0

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23

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42	
2/6	55	Reboxetine	Female		1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				19.PERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	32	32	27	17	9	4	3	3	3	3	3	3	3	3	3	3
	56	Reboxetine	Female		3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	3
				01.DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	3
				02.GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				03.SUICIDE	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2
				04.INSOMNIA EARLY	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1
				05.INSOMNIA MIDDLE	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	1
				06.INSOMNIA LATE	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	1
				07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08.RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09.AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2
				16.LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				17.INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18.DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19.PERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	29	29	25	24	24	24	19	18	18	18	18	18	18	18	18	23
	57	Imipramine	Female		3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	0
				01.DEPRESSED MOOD	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	0
				02.GUILT	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				03.SUICIDE	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0
				04.INSOMNIA EARLY	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	1
				08.RETARDATION	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0
				09.AGITATION	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0
				10.ANXIETY PSYCHIC	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	0
				11.ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				15.HYPOCHONDRIASIS	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				18.DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				19.PERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

1116

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24

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
2/6	57	Imipramine	Female	21. OBSESSIONAL/COMPULSIVE 22. Total score	1 30	1 30	0 25	0 15	0 5	0 4	0 1	0 2	
	58	Placebo	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3 1 1 0 0 0 3 2 0 2 3 2 1 0 0 0 0 0 0 0 0 0 26	3 1 1 0 0 0 3 2 0 2 3 2 1 0 0 0 0 0 0 0 0 26	3 1 1 0 0 0 3 2 0 2 3 2 1 0 0 0 0 0 0 0 0 26	2 1 1 0 0 0 2 1 0 1 0 0 0 0 0 0 0 0 0 0 0 22	0 0 0 0 0 0 2 1 0 1 0 0 0 0 0 0 0 0 0 0 0 6	0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 22	0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 24	0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 24	
	59	Placebo	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3 1 1 2 1 1 3 2 0 3 1 2 1 0 0 0 0 0 0 0 0 0 26	3 1 1 2 1 1 3 2 0 3 1 2 1 0 0 0 0 0 0 0 0 0 26	3 1 1 2 1 1 3 2 0 3 1 2 1 0 0 0 0 0 0 0 0 0 26	3 1 1 0 0 0 2 1 0 2 1 0 0 0 0 0 0 0 0 0 0 0 22	3 1 1 0 0 0 2 1 0 1 0 0 0 0 0 0 0 0 0 0 0 0 6	3 1 1 0 0 0 2 1 0 1 0 0 0 0 0 0 0 0 0 0 0 0 22	3 1 1 0 0 0 2 1 0 1 0 0 0 0 0 0 0 0 0 0 0 6	3 1 1 0 0 0 2 1 0 1 0 0 0 0 0 0 0 0 0 0 0 24	3 1 1 0 0 0 2 1 0 1 0 0 0 0 0 0 0 0 0 0 0 24

1117

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25

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
1	2/6	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	1	0	0	0	0		
				02. GUILT	0	0	0	0	0	0	0	0		
				03. SUICIDE	1	1	1	1	0	0	0	0	0	
				04. INSOMNIA EARLY	2	2	2	1	0	0	0	0	0	
				05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	0	0	
				06. INSOMNIA LATE	1	1	1	1	0	0	0	0	0	
				07. WORK AND ACTIVITIES	2	2	2	1	1	1	1	1	1	1
				08. RETARDATION	2	2	2	1	0	0	0	0	0	0
				09. AGITATION	2	2	2	1	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	2	1	0	0	0	0	0
				11. ANXIETY SOMATIC	1	1	1	1	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	1	1	1	1	1	1	1	1	1	1
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0	0	0	0	0
				22. Total score	28	28	26	13	4	3	2	2	2	2
3	3/1	Imipramine	Male	01. DEPRESSED MOOD	2	2	2	2	1	1	1	1		
				02. GUILT	2	2	2	1	0	0	0	0		
				03. SUICIDE	2	2	2	1	0	0	0	0		
				04. INSOMNIA EARLY	2	2	2	1	1	1	1	1		
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1		
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0		
				07. WORK AND ACTIVITIES	3	3	3	4	4	2	1	1		
				08. RETARDATION	2	2	2	2	1	1	1	1		
				09. AGITATION	0	0	0	0	0	0	0	0		
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1	1		
				11. ANXIETY SOMATIC	2	2	2	2	2	1	0	0		
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0		
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1		
				14. GENITAL SYMPTOMS	1	1	1	2	2	1	1	1		
				15. HYPOCHONDRIASIS	1	1	1	0	0	0	0	0		
				16. LOSS OF WEIGHT	1	1	1	0	0	0	0	0		
				17. INSIGHT	0	0	0	0	0	0	0	0		
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1		
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0		
				20. PARANOID	0	0	0	0	0	0	0	0		
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0		
				22. Total score	24	24	24	20	11	7	7	7		
6	6/2	Imipramine	Female	01. DEPRESSED MOOD	3	3	2	1	1	1	1	1		
				02. GUILT	2	2	1	1	1	1	0			
				03. SUICIDE	2	2	1	0	0	0	0			
				04. INSOMNIA EARLY	2	2	1	1	1	1	1			

9550082

26

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PHARMACIA CNS RD

REBOMETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/1	62	Imipramine	Female	05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	0				
				06. INSOMNIA LATE	1	1	0	1	0	0	0					
				07. WORK AND ACTIVITIES	4	4	3	2	1	1	0	0				
				08. RETARDATION	1	1	1	1	1	1	0	0				
				09. ACITATION	2	2	0	1	0	0	0	0				
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	1	1				
				11. ANXIETY SOMATIC	2	2	1	1	1	1	0	0				
				12. SOMATIC GASTROINTESTINAL	2	2	1	0	0	0	1	1				
				13. SOMATIC GENERAL	1	1	1	0	0	0	1	1				
				14. GENITAL SYMPTOMS	2	2	1	1	1	1	1	1				
				15. HYPOCHONDRIASIS	2	2	1	1	1	1	1	1				
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0				
				17. INSIGHT	0	0	0	0	0	0	0	0				
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0				
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0				
				20. PARANOIA	0	0	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0				
				22. Total score	29	29	16	12	8	7	5	5				
				63	63	Placebo	Male	01. DEPRESSED MOOD	3	3	3	2	2	1	1	1
								02. GUILT	2	2	2	2	1	1	1	
								03. SUICIDE	3	2	2	1	1	1	0	
								04. INSOMNIA EARLY	2	2	2	2	2	2	1	
05. INSOMNIA MIDDLE	1	2	2					1	1	0	0					
06. INSOMNIA LATE	1	1	1					1	1	1	0					
07. WORK AND ACTIVITIES	4	4	4					3	3	1	0					
08. RETARDATION	2	1	1					1	1	1	1					
09. ACITATION	1	1	1					1	1	1	1					
10. ANXIETY PSYCHIC	3	2	2					2	2	2	2					
11. ANXIETY SOMATIC	2	1	1					1	1	1	1					
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	0					
13. SOMATIC GENERAL	2	2	1					1	1	1	1					
14. GENITAL SYMPTOMS	2	2	1					1	1	1	1					
15. HYPOCHONDRIASIS	0	0	0					0	0	0	0					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	0	0	0					0	0	0	0					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOIA	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	30	26	26					21	21	13	10	10				
64	64	Placebo	Female	01. DEPRESSED MOOD	3	3	2	3	3	3	3	3				
				02. GUILT	2	2	2	2	2	2	2					
				03. SUICIDE	1	1	0	0	0	0	0					
				04. INSOMNIA EARLY	2	2	1	0	0	0	1					
				05. INSOMNIA MIDDLE	1	2	1	0	0	0	0					
				06. INSOMNIA LATE	0	1	1	0	0	0	1					
				07. WORK AND ACTIVITIES	3	3	3	4	4	4	4					
				08. RETARDATION	1	1	1	2	2	2	1					

1119

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27

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PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	64	Placebo	Female		2	2	2	1	1	1	1	0
				09. AGITATION	2	2	2	1	1	1	1	0
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	1	1	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	1	1	1	3	3	3	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	25	28	24	26	26	26	26	24
65		Reboxetine	Male		3	3	2	2	1	1	1	1
				01. DEPRESSED MOOD	3	2	2	2	1	1	1	1
				02. GUILT	2	2	2	1	1	1	0	0
				03. SUICIDE	3	3	2	1	1	0	0	0
				04. INSOMNIA EARLY	2	2	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	1	1	1	1	0	0
				06. INSOMNIA LATE	1	1	0	1	0	0	0	0
				07. WORK AND ACTIVITIES	4	4	2	2	1	1	1	1
				08. RETARDATION	2	2	1	1	1	1	1	1
				09. AGITATION	1	1	2	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	3	2	2	2	2	1	1
				11. ANXIETY SOMATIC	2	2	2	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	2	1	1	1	0	0	0
				13. SOMATIC GENERAL	2	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	1	2	1	1	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	31	31	21	19	12	11	8	8
66		Reboxetine	Male		3	3	2	1	1	1	1	1
				01. DEPRESSED MOOD	3	2	2	1	1	1	1	1
				02. GUILT	2	2	2	1	1	1	1	0
				03. SUICIDE	1	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	0	1	1
				05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	0
				06. INSOMNIA LATE	1	1	1	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	2
				08. RETARDATION	2	2	2	1	1	0	0	0
				09. AGITATION	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	2	2	2	1	0	1	1
				11. ANXIETY SOMATIC	2	2	2	2	1	0	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	1	1	0	0	1

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28

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/1	66	Reboxetine	Male	13. SOMATIC GENERAL	2	2	1	1	1	1	1				
				14. GENITAL SYMPTOMS	2	2	2	2	2	2					
				15. HYPOCHONDRIASIS	1	1	1	1	1	1					
				16. LOSS OF WEIGHT	0	0	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0					
				18. DIURNAL VARIATION	2	2	1	1	1	1					
				19. DEPERSONALIZATION	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0					
				22. Total score	28	27	23	15	14	9	11	10			
				139	139	Imipramine	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3
								02. GUILT	2	2	2	2	2	2	
								03. SUICIDE	1	1	1	1	1	1	
								04. INSOMNIA EARLY	0	0	0	0	0	0	
								05. INSOMNIA MIDDLE	1	1	1	1	1	1	
								06. INSOMNIA LATE	2	2	2	2	2	2	
								07. WORK AND ACTIVITIES	2	2	2	2	2	2	
								08. RETARDATION	2	2	2	2	2	2	
								09. ACITATION	0	0	0	0	0	0	
								10. ANXIETY PSYCHIC	3	3	3	3	3	3	
								11. ANXIETY SOMATIC	1	1	1	1	1	1	
								12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	
13. SOMATIC GENERAL	1	1	1					1	1	1					
14. GENITAL SYMPTOMS	1	1	1					1	1	1					
15. HYPOCHONDRIASIS	0	0	0					0	0	0					
16. LOSS OF WEIGHT	0	0	0					0	0	0					
17. INSIGHT	0	0	0	0	0	0									
18. DIURNAL VARIATION	2	2	2	2	2	2									
19. DEPERSONALIZATION	0	0	0	0	0	0									
20. PARANOID	0	0	0	0	0	0									
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0									
22. Total score	23	24	26	35	35	35									
140	140	Placebo	Male	01. DEPRESSED MOOD	2	2	1	1	1	1	1				
				02. GUILT	1	1	1	1	1	1					
				03. SUICIDE	1	1	1	1	1	1					
				04. INSOMNIA EARLY	1	1	1	1	1	1					
				05. INSOMNIA MIDDLE	1	1	1	1	1	1					
				06. INSOMNIA LATE	1	1	1	1	1	1					
				07. WORK AND ACTIVITIES	2	2	1	1	1	1					
				08. RETARDATION	2	2	2	2	2	2					
				09. ACITATION	1	1	0	0	0	0					
				10. ANXIETY PSYCHIC	3	3	2	2	2	2					
				11. ANXIETY SOMATIC	2	2	2	2	2	2					
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2					
				13. SOMATIC GENERAL	2	2	2	2	2	2					
				14. GENITAL SYMPTOMS	1	1	1	1	1	1					
				15. HYPOCHONDRIASIS	2	2	2	2	2	2					
				16. LOSS OF WEIGHT	2	2	2	2	2	2					

1121

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29

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PHARMACIA CNS R&D
 REMOXYLINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	140	Placebo	Male	17.INSIGHT	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22.Total score	28	28	25	15	11	10	9	6
	141	Placebo	Female	01.DEPRESSED MOOD	2	2	2	1	1	1	1	1
				02.GUILT	2	2	2	1	1	1	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	0	0	1	1	1
				05.INSOMNIA MIDDLE	1	1	1	0	0	0	0	0
				06.INSOMNIA LATE	1	1	1	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	2	1	1	1	1
				08.RETARDATION	2	2	2	1	0	1	1	0
				09.AGITATION	2	2	3	1	1	1	1	1
				10.ANXIETY PSYCHIC	2	2	2	2	2	2	1	1
				11.ANXIETY SOMATIC	2	2	2	2	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	2	2	1	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	1	1	1	1	1
				14.CENTRAL SYMPTOMS	2	2	2	1	1	1	1	1
				15.HYPOCHONDRIASIS	2	2	2	2	1	1	1	1
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17.INSIGHT	0	1	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22.Total score	23	25	24	17	9	12	9	9
	142	Imipramine	Female	01.DEPRESSED MOOD	2	2	2	2	2	2	2	2
				02.GUILT	2	2	2	2	2	2	2	2
				03.SUICIDE	2	2	2	2	2	2	2	2
				04.INSOMNIA EARLY	2	2	2	2	2	2	2	2
				05.INSOMNIA MIDDLE	2	2	2	2	2	2	2	2
				06.INSOMNIA LATE	2	2	2	2	2	2	2	2
				07.WORK AND ACTIVITIES	4	4	4	4	4	4	4	4
				08.RETARDATION	2	2	2	2	2	2	2	2
				09.AGITATION	2	2	2	2	2	2	2	2
				10.ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11.ANXIETY SOMATIC	3	3	3	3	3	3	3	3
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14.CENTRAL SYMPTOMS	1	1	1	1	1	1	1	1
				15.HYPOCHONDRIASIS	2	2	1	1	1	1	1	1
				16.LOSS OF WEIGHT	1	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0

1122

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30

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	142	Imipramine	Female	0	0	0	0	0	0	0
			21. OBSESSIONAL/COMPULSIVE	31	30	29	29	29	29	29
			22. Total score							
	143	Reboxetine	Female	3	3	2	2	1	1	1
			01. DEPRESSED MOOD	1	2	2	1	1	1	1
			02. GUILT	3	3	1	1	0	0	0
			03. SUICIDE	0	0	0	0	0	0	0
			04. INSOMNIA EARLY	1	1	1	1	1	1	1
			05. INSOMNIA MIDDLE	0	0	0	0	0	0	0
			06. INSOMNIA LATE	0	0	0	0	0	0	0
			07. WORK AND ACTIVITIES	3	3	2	2	1	1	1
			08. RETARDATION	1	1	1	1	1	1	1
			09. AGITATION	1	1	1	1	1	1	1
			10. ANXIETY PSYCHIC	2	2	2	1	1	1	1
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1
			13. SOMATIC GENERAL	2	2	2	1	1	1	1
			14. GENITAL SYMPTOMS	2	2	2	1	1	1	1
			15. HYPOCHONDRIASIS	1	1	1	0	0	0	0
			16. LOSS OF WEIGHT	0	0	0	0	0	0	0
			17. INSIGHT	0	0	0	0	0	0	0
			18. DIURNAL VARIATION	1	1	1	1	1	1	1
			19. DEPERSONALIZATION	0	0	0	0	0	0	0
			20. PARANOID	0	0	0	0	0	0	0
			21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0
			22. Total score	23	24	17	11	11	11	11
	144	Reboxetine	Female	3	3	3	1	0	0	0
			01. DEPRESSED MOOD	2	2	2	2	1	1	1
			02. GUILT	2	2	2	0	0	0	0
			03. SUICIDE	2	2	2	2	1	1	1
			04. INSOMNIA EARLY	2	2	2	2	0	0	0
			05. INSOMNIA MIDDLE	2	2	2	2	0	0	0
			06. INSOMNIA LATE	1	0	2	2	0	0	0
			07. WORK AND ACTIVITIES	2	2	2	2	1	1	1
			08. RETARDATION	2	2	2	1	1	1	1
			09. AGITATION	0	0	0	1	1	1	1
			10. ANXIETY PSYCHIC	3	3	3	3	2	2	2
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1
			12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0
			13. SOMATIC GENERAL	1	1	1	1	1	1	1
			14. GENITAL SYMPTOMS	1	1	1	1	1	1	1
			15. HYPOCHONDRIASIS	0	0	2	1	2	1	1
			16. LOSS OF WEIGHT	2	2	0	0	0	0	0
			17. INSIGHT	0	0	0	0	0	0	0
			18. DIURNAL VARIATION	0	0	0	0	0	0	0
			19. DEPERSONALIZATION	0	0	0	0	0	0	0
			20. PARANOID	0	0	0	0	0	0	0
			21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0
			22. Total score	24	23	26	14	13	10	9

11
12
13

PHARMACIA CNS R&D
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient Treatment	Sex	Hamilton depression rating scale											
3/1	451	Female	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Screen			Day	42
			HAMILTON DEPRESSION RATING SCALE											
			3	3	3	3	3	3	3	3	3	3	3	3
			2	2	2	2	2	2	2	2	2	2	2	2
			1	1	1	1	1	1	1	1	1	1	1	1
			2	2	2	2	2	2	2	2	2	2	2	2
			3	3	3	3	3	3	3	3	3	3	3	3
			0	0	0	0	0	0	0	0	0	0	0	0
			2	2	2	2	2	2	2	2	2	2	2	2
			2	2	2	2	2	2	2	2	2	2	2	2
			1	1	1	1	1	1	1	1	1	1	1	1
			2	2	2	2	2	2	2	2	2	2	2	2
			2	2	2	2	2	2	2	2	2	2	2	2
			1	1	1	1	1	1	1	1	1	1	1	1
			2	2	2	2	2	2	2	2	2	2	2	2
			2	2	2	2	2	2	2	2	2	2	2	2
			0	0	0	0	0	0	0	0	0	0	0	0
			2	2	2	2	2	2	2	2	2	2	2	2
			2	2	2	2	2	2	2	2	2	2	2	2
			1	1	1	1	1	1	1	1	1	1	1	1
			2	2	2	2	2	2	2	2	2	2	2	2
			2	2	2	2	2	2	2	2	2	2	2	2
			1	1	1	1	1	1	1	1	1	1	1	1
			2	2	2	2	2	2	2	2	2	2	2	2
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			25	26	24	24	24	27						
			3	3	3	3	3	3	3	3	3	3	3	3
			1	1	1	1	1	1	1	1	1	1	1	1
			0	0	0	0	0	0	0	0	0	0	0	0
			2	2	2	2	2	2	2	2	2	2	2	2
			2	2	2	2	2	2	2	2	2	2	2	2
			4	4	4	4	4	4	4	4	4	4	4	4
			2	2	2	2	2	2	2	2	2	2	2	2
			2	2	2	2	2	2	2	2	2	2	2	2
			2	2	2	2	2	2	2	2	2	2	2	2
			1	1	1	1	1	1	1	1	1	1	1	1
			2	2	2	2	2	2	2	2	2	2	2	2
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			26	25	15	6	2	1	11	6				
			3	3	3	3	3	3	3	3	3	3	3	3
			2	2	2	2	2	2	2	2	2	2	2	2
			0	0	0	0	0	0	0	0	0	0	0	0
			1	1	1	1	1	1	1	1	1	1	1	1
			26	25	15	6	2	1	11	6				

9550082

32

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
3/1	453	Female	Imipramine	05. INSOMNIA MIDDLE	1	1	1	1	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	1	1	1	1	1	1	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	2	2	2	1	1	1	1	1	1	1	1
				08. RETARDATION	2	2	1	1	1	0	0	0	0	0	0	0	0
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	2	2	2	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	24	24	17	16	16	10	9	9	9	9	9	9	10
4/4	454	Male	Reboxetine	01. DEPRESSED MOOD	2	2	1	1	1	1	0	0	0	0	0	0	0
				02. GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	2	2	2	1	1	1	1	1	1	1	1
				08. RETARDATION	2	2	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	25	24	13	12	12	8	7	7	7	7	7	7	8
4/5	455	Female	Placebo	01. DEPRESSED MOOD	3	3	3	3	2	2	2	2	2	2	2	2	2
				02. GUILT	2	1	2	2	2	1	1	1	1	1	1	1	1
				03. SUICIDE	2	2	2	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	3	3	3	3	3	3	2
				08. RETARDATION	3	3	3	2	2	2	1	1	1	1	1	1	1

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33

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/1	455	Placebo	Female	09. AGITATION	0	0	0	0	0	0	0	0				
				10. ANXIETY PSYCHIC	3	3	3	2	2	2	2					
				11. ANXIETY SOMATIC	0	0	0	0	0	0	0					
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0					
				13. SOMATIC GENERAL	2	2	2	2	2	2	2					
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2					
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	2	2	2	2	1	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	25	24	24	21	17	18	15					
				456	456	Imipramine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2
								02. GUILT	2	2	1	1	1	1	1	
								03. SUICIDE	1	1	0	0	0	0	0	
								04. INSOMNIA EARLY	2	2	1	0	0	0	0	
								05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	
								06. INSOMNIA LATE	1	1	1	0	0	0	0	
								07. WORK AND ACTIVITIES	4	4	3	3	3	3	3	
								08. RETARDATION	2	2	2	2	2	2	2	
09. AGITATION	0	0	0					1	1	1	1					
10. ANXIETY PSYCHIC	2	2	2					2	2	2	2					
11. ANXIETY SOMATIC	2	2	2					1	4	4	4					
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	0	0					
13. SOMATIC GENERAL	1	1	1	1	2	2	2									
14. GENITAL SYMPTOMS	2	2	2	2	2	2	2									
15. HYPOCHONDRIASIS	0	1	0	0	0	0	0									
16. LOSS OF WEIGHT	1	0	0	0	0	0	0									
17. INSIGHT	0	0	0	0	0	0	0									
18. DIURNAL VARIATION	0	0	0	0	0	0	0									
19. DEPERSONALIZATION	0	0	0	0	0	0	0									
20. PARANOID	0	0	0	0	0	0	0									
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0									
22. Total score	24	24	18	19	18	18	15									
3/2	65/A	Reboxetine	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2				
				02. GUILT	3	3	2	2	2	2	2					
				03. SUICIDE	3	3	2	1	2	2	2					
				04. INSOMNIA EARLY	2	1	2	1	1	1	1					
				05. INSOMNIA MIDDLE	2	0	2	2	1	1	1					
				06. INSOMNIA LATE	1	0	1	1	0	0	1					
				07. WORK AND ACTIVITIES	2	2	2	1	2	2	2					
				08. RETARDATION	1	2	1	1	2	2	1					
				09. AGITATION	2	1	2	1	1	0	0					
				10. ANXIETY PSYCHIC	3	3	2	2	3	1	2					
				11. ANXIETY SOMATIC	3	2	2	1	1	1	0					
				12. SOMATIC GASTROINTESTINAL	0	0	1	0	0	0	0					

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34

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PHARMACIA CNS R&D
REBOMETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/2	65/A	Reboxetine	Female	13. SOMATIC GENERAL	1	1	1	1	1	1	1				
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0				
				15. HYPOCHONDRIASIS	2	3	2	1	0	0	1	1			
				16. LOSS OF WEIGHT	0	0	2	0	0	0	0	0			
				17. INSIGHT	0	0	0	0	0	0	0	0			
				18. DIURNAL VARIATION	0	2	1	0	1	1	0	0			
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0			
				20. PARANOID	0	1	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0			
				22. Total score	27	25	27	17	19	17	17	19	18		
				3/3	67	Placebo	Male	01. DEPRESSED MOOD	3	3	3	1	2	2	2
								02. GUILT	1	1	1	1	0	0	0
								03. SUICIDE	3	2	1	3	0	0	0
								04. INSOMNIA EARLY	2	2	0	2	2	2	2
								05. INSOMNIA MIDDLE	1	1	0	1	0	0	0
								06. INSOMNIA LATE	0	1	0	0	0	0	0
								07. WORK AND ACTIVITIES	4	4	4	4	4	2	2
								08. RETARDATION	2	2	2	2	1	1	1
								09. AGITATION	0	0	0	0	0	0	0
								10. ANXIETY PSYCHIC	3	2	3	3	2	1	0
								11. ANXIETY SOMATIC	2	2	1	1	1	1	0
								12. SOMATIC GASTROINTESTINAL	2	0	0	0	0	0	0
13. SOMATIC GENERAL	1	1	1					1	1	1	0				
14. GENITAL SYMPTOMS	0	0	0					0	0	0	0				
15. HYPOCHONDRIASIS	1	1	1					1	0	1	0				
16. LOSS OF WEIGHT	1	0	1					0	0	2	0				
17. INSIGHT	1	0	0					0	0	0	0				
18. DIURNAL VARIATION	2	2	1					2	1	0	0				
19. DEPERSONALIZATION	1	1	0					1	0	0	0				
20. PARANOID	0	0	0					0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0				
22. Total score	28	25	19					25	13	13	13	7			
68	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	1	0	0	0	0				
			02. GUILT	3	3	2	0	0	0	0					
			03. SUICIDE	1	1	0	0	0	0	0					
			04. INSOMNIA EARLY	2	1	1	1	1	0	0					
			05. INSOMNIA MIDDLE	0	0	0	0	0	0	0					
			06. INSOMNIA LATE	1	1	0	0	0	0	0					
			07. WORK AND ACTIVITIES	3	4	3	1	0	0	0					
			08. RETARDATION	3	3	2	2	0	0	0					
			09. AGITATION	0	0	0	0	0	0	0					
			10. ANXIETY PSYCHIC	1	2	1	1	0	0	0					
			11. ANXIETY SOMATIC	2	2	1	1	0	0	0					
			12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0					
			13. SOMATIC GENERAL	1	1	0	0	1	0	0					
			14. GENITAL SYMPTOMS	0	0	0	0	0	0	0					
			15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
			16. LOSS OF WEIGHT	2	0	0	0	0	0	0					

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/3	68	Reboxetine	Male	17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSSIONAL/COMPULSIVE 22. Total score	1 0 0 0 0 23	1 0 0 0 0 23	1 0 0 0 0 15	0 0 0 0 0 9	0 0 0 0 0 3	0 0 0 0 0 1	0 0 0 0 0 1	0 0 0 0 0 0
	69	Placebo	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSSIONAL/COMPULSIVE 22. Total score	4 2 2 2 1 1 4 2 2 3 3 1 1 1 0 2 1 0 0 3 3 3 1 1 1 1 0 0 0 0 33	3 2 1 2 0 0 4 2 2 4 3 3 2 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	3 2 1 2 1 0 4 2 2 4 3 3 2 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 3 1 1 0 0 2 1 1 2 2 1 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 0 0 0 0 0 2 1 1 1 2 2 1 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	4 3 2 1 1 0 1	2 2 0 0 0 0 1	
	70	Imipramine	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID	4 2 2 1 2 2 3 2 2 2 3 2 2 2 2 3 2 1 0 0 3 3 3 2 2 2 2 2 3	3 2 1 1 0 2 2 2 2 2 2 2 2 2 2 2 2 1 0 0 1 1 1 1 1 1 1 1 1	3 2 1 1 0 2 2 2 2 2 2 2 2 2 2 2 2 1 0 0 2 2 2 2 2 2 2 2 2	2 2 0 0 0 2 2 2 2 2 2 2 2 2 2 2 2 1 0 0 1 1 1 1 1 1 1 1 1	1 0 0 0 0 0 2 1	1 1 0 0 0 0 2 1	1 0 0 0 0 0 2 1	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
3/3	70	Imipramine	Male	21. OBSESSIONAL/COMPULSIVE	1	1	1	1	0	1	0	0		
			Female	22. Total score	36	31	21	15	10	13	8	8	8	
71	Imipramine	Female	01. DEPRESSED MOOD	4	3	2	2	1	1	1	1	1		
			02. GUILT	3	3	2	2	2	2	2	2	2	1	
			03. SUICIDE	2	1	0	0	0	0	0	0	0	0	0
			04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0	0
			05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0
			06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0
			07. WORK AND ACTIVITIES	3	3	3	2	1	1	0	0	0	0	0
			08. RETARDATION	2	2	0	0	0	0	0	0	0	0	0
			09. AGITATION	1	1	1	1	1	0	0	0	0	0	0
			10. ANXIETY PSYCHIC	3	2	2	2	1	1	1	0	0	0	0
			11. ANXIETY SOMATIC	2	2	2	2	1	1	1	0	0	0	0
			12. SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0	0	0	0
			13. SOMATIC GENERAL	2	2	1	1	1	1	1	1	1	1	1
			14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0
			15. HYPOCHONDRIASIS	1	1	1	1	1	0	0	0	0	0	0
			16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0
			17. INSIGHT	1	1	1	1	0	0	0	0	0	0	0
			18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0
			19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0
			20. PARANOID	0	0	0	0	0	0	0	0	0	0	0
			21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1
			22. Total score	26	23	17	12	8	7	5	4	4	4	4
72	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	1	1	1	1	1		
			02. GUILT	3	2	2	2	2	2	2	2	2	1	
			03. SUICIDE	2	1	1	0	0	0	0	0	0	0	0
			04. INSOMNIA EARLY	2	2	1	0	0	0	0	0	0	0	0
			05. INSOMNIA MIDDLE	1	0	0	0	0	0	0	0	0	0	0
			06. INSOMNIA LATE	1	0	0	0	0	0	0	0	0	0	0
			07. WORK AND ACTIVITIES	2	2	1	0	0	0	0	0	0	0	0
			08. RETARDATION	1	1	1	1	1	1	1	1	1	1	0
			09. AGITATION	2	1	1	0	0	0	0	0	0	0	0
			10. ANXIETY PSYCHIC	1	2	1	1	1	1	2	1	1	1	1
			11. ANXIETY SOMATIC	2	1	0	1	1	1	0	0	0	0	0
			12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	0	0	0
			13. SOMATIC GENERAL	1	1	0	0	0	0	0	0	0	0	0
			14. GENITAL SYMPTOMS	2	1	0	0	0	0	0	0	0	0	0
			15. HYPOCHONDRIASIS	1	1	0	1	1	1	0	0	0	0	0
			16. LOSS OF WEIGHT	2	0	0	0	0	0	0	0	0	0	0
			17. INSIGHT	1	0	0	0	0	0	0	0	0	0	0
			18. DIURNAL VARIATION	2	2	2	1	0	1	1	1	1	1	1
			19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0
			20. PARANOID	0	0	0	0	0	0	0	0	0	0	0
			21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1
			22. Total score	31	22	13	10	7	8	5	12	8	5	12

1129

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37

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/4	79	Imipramine	Female	01. DEPRESSED MOOD	4	4	2	2	1	0	0	0
				02. GUILT	1	1	1	1	1	0	0	0
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	0	0	0	0
				06. INSOMNIA LATE	1	1	1	1	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	2	2	1	0	0	0
				08. RETARDATION	2	2	2	1	0	0	0	0
				09. AGITATION	1	1	0	0	1	0	0	0
				10. ANXIETY PSYCHIC	3	3	2	2	2	1	0	0
				11. ANXIETY SOMATIC	2	2	2	2	1	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	0	0	0	0
				15. HYPOCHONDRIASIS	2	2	2	2	1	1	1	1
				16. LOSS OF WEIGHT	2	2	3	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	29	29	24	20	15	4	3	3
80		Imipramine	Male	01. DEPRESSED MOOD	2	2	2	2	1	1	1	1
				02. GUILT	1	1	1	1	1	1	1	1
				03. SUICIDE	3	3	3	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	0	0	0	0	0	0
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	1	1	1	1	1
				08. RETARDATION	2	2	2	1	1	1	1	1
				09. AGITATION	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	2	2	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	2	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0	0
				13. SOMATIC GENERAL	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	1	1	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	2	2	2	2	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	22	24	21	14	10	10	10	10
81		Reboxetine	Female	01. DEPRESSED MOOD	3	3	1	1	1	1	1	1
				02. GUILT	2	2	1	0	0	1	1	1
				03. SUICIDE	3	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	0	0	0	0	0	0

1130

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39

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42	
3/4	83	Placebo	Male		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23
84		Reboxetine	Female		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24
85		Imipramine	Female		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2

1132

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40

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PHARMACIA CNS R&D
 XEROMETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/4	85	Imipramine	Female	13. SOMATIC GENERAL	2	2	1	1	1	1	1	0				
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	1	0	0	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	1	1	1	0	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	28	27	20	11	10	17	10	4				
				86	Imipramine	Male	01. DEPRESSED MOOD	4	4	2	1	1	1	1	1	1
							02. GUILT	1	1	1	1	0	0	0		
							03. SUICIDE	3	3	0	0	0	0	0		
							04. INSOMNIA EARLY	1	1	1	0	0	0	0		
							05. INSOMNIA MIDDLE	1	1	1	0	0	0	0		
							06. INSOMNIA LATE	1	1	1	0	0	0	0		
							07. WORK AND ACTIVITIES	2	2	2	1	1	1	1		
							08. RETARDATION	2	2	2	1	1	1	1		
							09. AGITATION	1	1	1	0	0	0	0		
							10. ANXIETY PSYCHIC	1	1	1	0	0	0	0		
							11. ANXIETY SOMATIC	3	3	2	2	1	1	1		
							12. SOMATIC GASTROINTESTINAL	2	2	2	1	1	1	1		
13. SOMATIC GENERAL	1	1	1				1	1	1	1						
14. GENITAL SYMPTOMS	1	1	1				0	0	0	0						
15. HYPOCHONDRIASIS	1	1	1				0	0	0	0						
16. LOSS OF WEIGHT	0	0	0				0	0	0	0						
17. INSIGHT	0	0	0				0	0	0	0						
18. DIURNAL VARIATION	2	2	2				0	0	0	0						
19. DEPERSONALIZATION	0	0	0				0	0	0	0						
20. PARANOID	0	0	0				0	0	0	0						
21. OBSESSIONAL/COMPULSIVE	0	0	0				0	0	0	0						
22. Total score	28	28	19				9	6	4	5						
87	Placebo	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	3	2	2				
			02. GUILT	2	2	2	2	2	2	2						
			03. SUICIDE	3	3	2	1	1	3	1						
			04. INSOMNIA EARLY	1	1	1	0	0	2	1						
			05. INSOMNIA MIDDLE	2	2	1	0	0	1	0						
			06. INSOMNIA LATE	1	1	1	0	0	0	0						
			07. WORK AND ACTIVITIES	2	2	1	1	1	3	1						
			08. RETARDATION	4	4	1	1	0	1	1						
			09. AGITATION	1	1	1	1	1	2	1						
			10. ANXIETY PSYCHIC	1	1	1	1	1	2	1						
			11. ANXIETY SOMATIC	3	3	3	2	2	3	2						
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	2	1						
			13. SOMATIC GENERAL	1	1	1	1	1	1	1						
			14. GENITAL SYMPTOMS	1	1	1	1	1	2	1						
			15. HYPOCHONDRIASIS	1	1	1	1	1	1	1						
			16. LOSS OF WEIGHT	0	0	0	0	0	0	0						

1133

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41

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
3/4	87	Placebo	Female	17. INSIGHT	0	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1				
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0			
				20. PARANOID	0	0	0	0	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0			
				22. Total score	24	24	21	15	12	27	16	12					
				88	88	Placebo	Male	01. DEPRESSED MOOD	2	2	1	1	1	1	1	1	
								02. GUILT	0	0	0	0	0	0	0	0	0
								03. SUICIDE	0	0	0	0	0	0	0	0	0
								04. INSOMNIA EARLY	2	2	1	0	0	0	0	0	0
								05. INSOMNIA MIDDLE	1	1	0	0	0	0	0	0	0
								06. INSOMNIA LATE	1	1	1	0	0	0	0	0	0
07. WORK AND ACTIVITIES	2	2	1					1	1	1	1	1	1				
08. RETARDATION	2	2	2					1	1	1	1	1	1				
09. AGITATION	1	1	0					0	0	0	0	0	0				
10. ANXIETY PSYCHIC	3	3	2					1	1	1	1	1	1				
11. ANXIETY SOMATIC	2	2	2					2	1	1	1	1	1				
12. SOMATIC GASTROINTESTINAL	1	1	0					0	0	0	0	0	0				
13. SOMATIC GENERAL	2	2	2	2	1	1	1	1	1								
14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1								
15. HYPOCHONDRIASIS	3	3	3	2	2	2	2	2	2								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0								
17. INSIGHT	0	0	0	0	0	0	0	0	0								
18. DIURNAL VARIATION	1	2	2	2	2	2	2	2	2								
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0								
20. PARANOID	0	0	0	0	0	0	0	0	0								
21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1								
22. Total score	25	26	19	14	11	8	7	6									
89	89	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	1					
				02. GUILT	1	1	1	1	1	1	1	1					
				03. SUICIDE	0	0	0	0	0	0	0	0					
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2					
				05. INSOMNIA MIDDLE	1	1	0	0	0	0	0	0					
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	0	3	2	2	1	1	1	1					
				08. RETARDATION	2	2	2	2	1	1	1	1					
				09. AGITATION	1	1	0	0	0	0	0	0					
				10. ANXIETY PSYCHIC	3	3	3	2	2	2	2	2					
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2					
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0					
13. SOMATIC GENERAL	2	2	1	1	2	2	1	1									
14. GENITAL SYMPTOMS	2	2	2	2	1	1	1	1									
15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1									
16. LOSS OF WEIGHT	2	2	1	0	1	1	0	0									
17. INSIGHT	0	0	0	0	0	0	0	0									
18. DIURNAL VARIATION	1	1	1	1	1	1	1	1									
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0									
20. PARANOID	0	0	0	0	0	0	0	0									

1134

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42

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/4	89	Reboxetine	Female	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
			22. Total score	25	26	22	20	19	18	12	10	
90		Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	3	3	2	1	1
				02. GUILT	2	2	2	2	2	1	0	0
				03. SUICIDE	1	1	1	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	0	0	0	0	0
				05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	0
				06. INSOMNIA LATE	1	1	1	0	0	0	0	0
				07. WORK AND ACTIVITIES	2	2	2	1	1	0	0	0
				08. RETARDATION	1	1	1	1	1	0	0	0
				09. AGITATION	2	2	2	2	2	1	0	0
				10. ANXIETY PSYCHIC	3	3	3	2	2	1	0	0
				11. ANXIETY SOMATIC	2	2	2	2	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	1	1	0	0
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0	0	0
				22. Total score	24	24	24	24	16	13	9	3
457		Placebo	Female	01. DEPRESSED MOOD	3	2	3	3	3	3	3	3
				02. GUILT	1	1	2	2	2	2	2	
				03. SUICIDE	2	2	2	2	2	2	2	
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	
				06. INSOMNIA LATE	2	2	2	2	2	2	2	
				07. WORK AND ACTIVITIES	4	4	4	4	3	3	3	
				08. RETARDATION	2	2	2	2	2	2	2	
				09. AGITATION	1	1	1	1	1	1	1	
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	
				13. SOMATIC GENERAL	4	4	4	4	4	4	4	
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	
				17. INSIGHT	0	0	0	0	0	0	0	
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	
				20. PARANOID	0	0	0	0	0	0	0	
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	
				22. Total score	28	27	30	27	28	28		

1135

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43

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
3/4	458	Reboxetine Female	HAMILTON DEPRESSION RATING SCALE							
		01. DEPRESSED MOOD	2	2	2	3				
		02. GUILT	2	2	2	2				
		03. SUICIDE	1	1	1	3				
		04. INSOMNIA EARLY	1	1	1	1				
		05. INSOMNIA MIDDLE	0	0	1	1				
		06. INSOMNIA LATE	1	1	1	1				
		07. WORK AND ACTIVITIES	3	2	3	3				
		08. RETARDATION	1	1	1	1				
		09. AGITATION	1	1	1	2				
		10. ANXIETY PSYCHIC	3	3	3	3				
		11. ANXIETY SOMATIC	4	4	4	4				
		12. SOMATIC GASTROINTESTINAL	1	1	2	2				
		13. SOMATIC GENERAL	2	2	2	2				
		14. GENITAL SYMPTOMS	2	2	2	2				
		15. HYPOCHONDRIASIS	3	3	3	3				
		16. LOSS OF WEIGHT	0	0	0	0				
		17. INSIGHT	1	1	1	0				
		18. DIURNAL VARIATION	0	0	0	0				
		19. DEPERSONALIZATION	0	0	0	0				
		20. PARANOID	0	0	0	0				
		21. OBSESSIONAL/COMPULSIVE	0	0	0	0				
		22. Total score	28	27	29	33				
		01. DEPRESSED MOOD	3	3	2	2	1	1	1	
		02. GUILT	1	1	1	1	0	0	0	
		03. SUICIDE	1	1	0	0	0	0	0	
		04. INSOMNIA EARLY	1	1	1	1	0	0	0	
		05. INSOMNIA MIDDLE	1	1	0	0	0	0	0	
		06. INSOMNIA LATE	1	1	1	1	0	0	0	
		07. WORK AND ACTIVITIES	2	2	2	1	1	1	1	
		08. RETARDATION	2	2	1	1	1	1	0	
		09. AGITATION	2	2	2	2	2	1	1	
		10. ANXIETY PSYCHIC	2	2	2	2	2	1	1	
		11. ANXIETY SOMATIC	3	3	2	2	2	1	1	
		12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	
		13. SOMATIC GENERAL	1	1	1	1	1	1	1	
		14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	
		15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	
		16. LOSS OF WEIGHT	1	1	0	0	0	0	0	
		17. INSIGHT	1	1	0	0	0	0	0	
		18. DIURNAL VARIATION	0	0	0	0	0	0	0	
		19. DEPERSONALIZATION	0	0	0	0	0	0	0	
		20. PARANOID	0	0	0	0	0	0	0	
		21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	
		22. Total score	26	26	19	18	16	11	8	
		01. DEPRESSED MOOD	1	1	1	1	1	1	1	
		02. GUILT	0	0	0	0	0	0	0	
		03. SUICIDE	0	0	0	0	0	0	0	
		04. INSOMNIA EARLY	2	2	2	1	1	1	1	

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1136

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45

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
3/4	462	Imipramine	Female		1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. ACITATION	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	22	22	22	22	22	22	22	22	22	22	22	22	22	22
4/1	91	Imipramine	Female		3	3	3	3	3	3	3	3	3	3	3	3	3	3
				01. DEPRESSED MOOD	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. MORE AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. ACITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	27	25	16	12	10	10	7	7	7	7	7	7	7
92		Reboxetine	Female		2	2	2	2	2	2	2	2	2	2	2	2	2	2
				01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. MORE AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				08. RETARDATION	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				09. ACITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1

1138

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46

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42							
4/1	92	Reboxetine	Female	13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1						
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				16. LOSS OF WEIGHT	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				19. DEPERSONALIZATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
				22. Total score	37	37	37	37	36	36	38	38	39	39	37	37	37	38	37	37	37	38			
				93	93	Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	2	2	1	1	1	1	1	0		
								02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
								03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
								07. WORK AND ACTIVITIES	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								10. ANXIETY PSYCHIC	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2
								11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
13. SOMATIC GENERAL	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1				
14. GENITAL SYMPTOMS	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0				
15. HYPOCHONDRIASIS	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1				
16. LOSS OF WEIGHT	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0				
17. INSIGHT	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0				
18. DIURNAL VARIATION	1	1	1					1	1	1	2	2	2	2	2	2	2	2	2	2	2				
19. DEPERSONALIZATION	1	1	1					1	1	1	2	2	2	2	2	2	2	2	2	2	2				
20. PARANOID	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0				
22. Total score	29	29	26					26	36	36	21	21	6	6	6	6	6	6	6	6	6				
94	94	Placebo	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	2	2	2	2	2	2	2	2	0						
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
				11. ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					

1139

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47

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
4/1	94	Placebo	Female		1	1	1	1	1	1	1	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	32	32	32	32	32	32	32	27	24	24	24	24	24	24
95		Imipramine	Female		3	3	3	3	3	3	3	1	1	1	1	1	1	0
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	1	1	1	1	1	1	0
				02. GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				07. MORE AND ACTIVITIES	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				08. RETARDATION	3	3	3	3	3	3	3	3	3	3	3	3	3	0
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	0
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				13. SOMATIC GENERAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	24	24	24	24	24	24	24	24	24	24	24	24	24	24
96		Reboxetine	Female		3	3	3	3	3	3	3	2	2	2	2	2	2	1
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				02. GUILT	3	3	3	3	3	3	3	3	3	3	3	3	3	1
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				07. MORE AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	1
				08. RETARDATION	3	3	3	3	3	3	3	3	3	3	3	3	3	1
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	1
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				22. Total score	1	1	1	1	1	1	1	1	1	1	1	1	1	0

1140

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48

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PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	96	Reboxetine	Female	21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1
				22. Total score	36	36	27	24	17	15	16	15
115		Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	1	1
				02. GUILT	2	2	1	1	1	1	1	1
				03. SUICIDE	2	2	1	1	1	1	1	1
				04. INSOMNIA EARLY	2	2	2	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	0	0
				06. INSOMNIA LATE	2	2	2	1	1	1	1	1
				07. WORK AND ACTIVITIES	4	4	3	2	2	2	2	2
				08. RETARDATION	2	2	2	2	1	1	1	1
				09. AGITATION	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	3	2	2	1	1	1	1
				11. ANXIETY SOMATIC	3	2	2	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	1	1	1	1
				15. HYPOCHONDRIASIS	2	2	2	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	1	1	1	1
				17. INSIGHT	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	1	1	0	0	0	0	0	0
				20. PARANOID	1	1	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	0
				22. Total score	34	33	27	22	20	19	17	15
116		Imipramine	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2
				03. SUICIDE	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4
				08. RETARDATION	2	2	2	2	2	2	2	2
				09. AGITATION	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	1	1	1	1	1	1	1	1
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1
				22. Total score	30	27	30	27	30	27	30	27

1141

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49

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	117	Imipramine	Female			3	2	2	1	1	1	1
				01. DEPRESSED MOOD		3	2	2	1	1	1	1
				02. GUILT		3	2	1	1	1	1	1
				03. SUICIDE		3	2	1	0	0	0	0
				04. INSOMNIA EARLY		2	1	1	1	1	1	1
				05. INSOMNIA MIDDLE		2	1	0	0	0	0	0
				06. INSOMNIA LATE		2	1	0	0	0	0	0
				07. WORK AND ACTIVITIES		4	3	2	2	0	0	0
				08. RETARDATION		3	2	1	0	0	0	0
				09. AGITATION		3	2	1	1	1	1	1
				10. ANXIETY PSYCHIC		3	2	1	0	0	0	0
				11. ANXIETY SOMATIC		2	2	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL		1	1	1	1	1	1	1
				13. SOMATIC GENERAL		1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS		2	1	1	1	1	1	1
				15. HYPOCHONDRIASIS		0	0	0	0	0	0	0
				16. LOSS OF WEIGHT		0	0	0	0	0	0	0
				17. INSIGHT		0	0	0	0	0	0	0
				18. DIURNAL VARIATION		2	1	1	0	0	0	0
				19. DEPERSONALIZATION		1	1	0	0	0	0	0
				20. PARANOID		1	1	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE		1	1	0	0	0	0	0
				22. Total score		41	26	16	10	8	8	9
118		Reboxetine	Female			2	2	2	1	1	1	1
				01. DEPRESSED MOOD		2	2	2	1	1	1	1
				02. GUILT		1	2	2	1	0	0	0
				03. SUICIDE		1	2	1	1	1	1	1
				04. INSOMNIA EARLY		1	1	1	0	0	0	0
				05. INSOMNIA MIDDLE		1	1	1	0	0	0	0
				06. INSOMNIA LATE		1	1	1	0	0	0	0
				07. WORK AND ACTIVITIES		3	3	2	2	1	1	1
				08. RETARDATION		2	1	1	1	1	1	1
				09. AGITATION		1	1	1	1	0	0	0
				10. ANXIETY PSYCHIC		3	2	2	2	1	1	1
				11. ANXIETY SOMATIC		2	2	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL		1	1	1	0	0	0	0
				13. SOMATIC GENERAL		1	1	1	0	0	0	0
				14. GENITAL SYMPTOMS		2	2	1	1	1	1	1
				15. HYPOCHONDRIASIS		2	1	1	0	0	0	0
				16. LOSS OF WEIGHT		0	1	1	0	0	0	0
				17. INSIGHT		1	1	1	1	1	1	1
				18. DIURNAL VARIATION		0	2	0	0	0	0	0
				19. DEPERSONALIZATION		0	0	0	0	0	0	0
				20. PARANOID		0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE		0	0	0	0	0	0	0
				22. Total score		26	27	20	15	9	9	9
119		Placebo	Female			2	2	2	1	1	1	1
				01. DEPRESSED MOOD		2	2	2	1	1	1	1
				02. GUILT		2	2	1	1	1	1	1
				03. SUICIDE		0	0	0	0	0	0	0
				04. INSOMNIA EARLY		1	1	1	0	0	0	0

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42	
4/1	119	Placebo	Female	05. INSOMNIA MIDDLE	1		1													
				06. INSOMNIA LATE	2		2													
				07. WORK AND ACTIVITIES	3		3													
				08. RETARDATION	1		1													
				09. AGITATION	2		2													
				10. ANXIETY PSYCHIC	3		3													
				11. ANXIETY SOMATIC	3		3													
				12. SOMATIC GASTROINTESTINAL	2		2													
				13. SOMATIC GENERAL	2		2													
				14. GENITAL SYMPTOMS	1		1													
				15. HYPOCHONDRIASIS	1		1													
				16. LOSS OF WEIGHT	2		2													
				17. INSIGHT	1		1													
				18. DIURNAL VARIATION	0		0													
				19. DEPERSONALIZATION	1		1													
				20. PARANOID	0		0													
				21. OBSESSIONAL/COMPULSIVE	0		0													
				22. Total score	28		28													
120		Placebo	Female	01. DEPRESSED MOOD	2		2			2		2		2		2		2		2
				02. GUILT	1		1			1		1		1		1		1		1
				03. SUICIDE	1		1			1		1		1		1		1		1
				04. INSOMNIA EARLY	1		1			1		1		1		1		1		1
				05. INSOMNIA MIDDLE	1		1			1		1		1		1		1		1
				06. INSOMNIA LATE	1		1			1		1		1		1		1		1
				07. WORK AND ACTIVITIES	1		1			1		1		1		1		1		1
				08. RETARDATION	2		2			2		2		2		2		2		2
				09. AGITATION	2		2			2		2		2		2		2		2
				10. ANXIETY PSYCHIC	3		3			3		3		3		3		3		3
				11. ANXIETY SOMATIC	1		1			1		1		1		1		1		1
				12. SOMATIC GASTROINTESTINAL	2		2			2		2		2		2		2		2
				13. SOMATIC GENERAL	1		1			1		1		1		1		1		1
				14. GENITAL SYMPTOMS	2		2			2		2		2		2		2		2
				15. HYPOCHONDRIASIS	1		1			1		1		1		1		1		1
				16. LOSS OF WEIGHT	0		0			0		0		0		0		0		0
				17. INSIGHT	1		1			1		1		1		1		1		1
				18. DIURNAL VARIATION	0		0			0		0		0		0		0		0
				19. DEPERSONALIZATION	0		0			0		0		0		0		0		0
				20. PARANOID	0		0			0		0		0		0		0		0
				21. OBSESSIONAL/COMPULSIVE	0		0			0		0		0		0		0		0
				22. Total score	24		24			20		16		14		12		11		9
145		Imipramine	Female	01. DEPRESSED MOOD	3		3			3		3		3		3		3		3
				02. GUILT	3		3			3		3		3		3		3		3
				03. SUICIDE	2		2			2		2		2		2		2		2
				04. INSOMNIA EARLY	1		1			1		1		1		1		1		1
				05. INSOMNIA MIDDLE	2		2			2		2		2		2		2		2
				06. INSOMNIA LATE	2		2			2		2		2		2		2		2
				07. WORK AND ACTIVITIES	3		3			3		3		3		3		3		3
				08. RETARDATION	3		3			3		3		3		3		3		3

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42										
4/1	145	Imipramine	Female	09. ACITATION	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1									
				10. ANXIETY PSYCHIC	3	3	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1							
				11. ANXIETY SOMATIC	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				14. GENITAL SYMPTOMS	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				15. HYPOCHONDRIASIS	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				20. PARANOID	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				22. Total score	35	34	22	15	15	15	15	15	14	12														
				146	146	Placebo	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
								02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
								03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
								04. INSOMNIA EARLY	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
								05. INSOMNIA MIDDLE	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
								06. INSOMNIA LATE	2	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
								07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
09. ACITATION	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
10. ANXIETY PSYCHIC	3	3	3					3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
11. ANXIETY SOMATIC	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2								
14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2								
15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0								
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0								
20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0								
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0								
22. Total score	28	28	22	19	15	13	12	10																				
147	147	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2									
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2							
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
				07. WORK AND ACTIVITIES	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				09. ACITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				11. ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				

1144

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52

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day			
4/1	Reboxetine	Female	13.SOMATIC GENERAL	2	2	2	2	1	1	1	1			
			14.GENITAL SYMPTOMS	2	2	2	2	1	1	1	1			
			15.HYPCHONDRIASIS	1	1	1	1	1	1	1	1	1		
			16.LDSS OF HEIGHT	1	0	0	0	0	0	0	0	0		
			17.INSIGHT	1	1	1	1	1	1	1	1	1		
			18.DIURNAL VARIATION	1	1	1	1	1	1	1	1	1		
			19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0		
			20.PARANOID	0	0	0	0	0	0	0	0	0		
			21.OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0	0	0	0		
			22.Total score	32	31	28	28	22	20	19	17			
			148	Imipramine	Female	01.DEPRESSED MOOD	3	3	1	1	1	1	1	1
						02.GUILT	3	3	2	2	2	1	1	1
						03.SUICIDE	2	2	1	1	1	1	1	1
						04.INSOMNIA EARLY	1	1	1	1	1	1	1	1
						05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1
						06.INSOMNIA LATE	1	1	1	1	1	1	0	0
						07.WORK AND ACTIVITIES	3	3	2	2	1	1	1	1
						08.RETARDATION	2	2	2	2	1	1	1	1
						09.AGITATION	2	2	1	1	1	1	1	1
						10.ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
						11.ANXIETY SOMATIC	2	2	1	1	1	1	1	1
						12.SOMATIC GASTROINTESTINAL	2	2	2	2	1	1	1	1
13.SOMATIC GENERAL	1	1				1	1	1	1	1	0			
14.GENITAL SYMPTOMS	1	1				1	1	1	1	1	1			
15.HYPCHONDRIASIS	0	0				0	0	0	0	0	0			
16.LDSS OF HEIGHT	0	0				0	0	0	0	0	0			
17.INSIGHT	1	1	1	1	1	1	1	1						
18.DIURNAL VARIATION	0	0	0	0	0	0	0	0						
19.DEPERSONALIZATION	0	0	0	0	0	0	0	0						
20.PARANOID	0	0	0	0	0	0	0	0						
21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0						
22.Total score	27	26	22	20	17	17	14	12						
149	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	2	2	1	1	1			
			02.GUILT	3	3	2	2	1	1	1	1			
			03.SUICIDE	1	1	1	1	1	1	1	1			
			04.INSOMNIA EARLY	1	1	1	1	1	1	1	1			
			05.INSOMNIA MIDDLE	1	1	1	1	1	1	0	0			
			06.INSOMNIA LATE	1	1	1	1	1	1	1	1			
			07.WORK AND ACTIVITIES	3	3	3	2	2	2	1	1			
			08.RETARDATION	2	2	2	2	2	2	1	1			
			09.AGITATION	1	1	1	1	1	1	1	1			
			10.ANXIETY PSYCHIC	2	2	2	2	1	1	1	1			
			11.ANXIETY SOMATIC	2	2	2	2	1	1	1	1			
			12.SOMATIC GASTROINTESTINAL	1	1	1	1	2	1	1	1			
			13.SOMATIC GENERAL	2	2	2	2	2	1	1	1			
			14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1			
			15.HYPCHONDRIASIS	1	1	1	1	1	1	1	1			
			16.LDSS OF HEIGHT	1	1	1	1	1	1	1	1			

1145

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54

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/2	93/A	Male	21. OBSESSIONAL/COMPULSIVE 22. Total score	33	1	1	0	1	0	0	0
	99/A	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	33	3	2	2	2	1	0	0
	104	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	35	3	3	2	2	2	2	2

1147

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/3	97	Placebo	Male	01. DEPRESSED MOOD	2	2	2	2	2	3	3	3
				02. GUILT	2	2	2	2	2	2	2	
				03. SUICIDE	1	1	1	1	1	1	1	
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	
				06. INSOMNIA LATE	1	1	2	2	2	1	1	
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	
				08. RETARDATION	1	1	1	1	1	1	1	
				09. AGITATION	0	0	0	0	0	0	0	
				10. ANXIETY PSYCHIC	4	3	3	3	3	3	3	
				11. ANXIETY SOMATIC	3	2	2	2	2	2	2	
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	
				14. GENITAL SYMPTOMS	1	2	2	2	2	2	2	
				15. HYPOCHONDRIASIS	3	3	3	3	3	3	3	
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	
				17. INSIGHT	0	0	0	0	0	0	0	
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	
				20. PARANOID	0	0	0	0	0	0	0	
				21. OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	
				22. Total score	24	27	25	25	27	27	27	
98		Reboxetine	Female	01. DEPRESSED MOOD	2	2	3	3	2	2	2	3
				02. GUILT	2	2	2	2	2	2	2	
				03. SUICIDE	1	1	1	1	1	1	1	
				04. INSOMNIA EARLY	1	1	2	2	1	1	1	
				05. INSOMNIA MIDDLE	1	1	2	2	1	1	2	
				06. INSOMNIA LATE	1	1	2	2	1	1	2	
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	
				08. RETARDATION	1	1	2	2	1	1	2	
				09. AGITATION	1	1	1	1	1	1	2	
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	2	
				11. ANXIETY SOMATIC	2	2	2	2	1	1	2	
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	2	
				13. SOMATIC GENERAL	1	1	1	1	1	1	2	
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	2	
				15. HYPOCHONDRIASIS	3	3	2	2	2	2	3	
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	
				17. INSIGHT	1	1	0	0	1	1	0	
				18. DIURNAL VARIATION	1	1	1	1	1	1	0	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	
				20. PARANOID	0	0	0	0	0	0	0	
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	0	
				22. Total score	25	25	28	32	22	22	30	
99		Placebo	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3
				02. GUILT	3	3	3	3	3	3	3	
				03. SUICIDE	1	1	1	1	1	1	1	
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	

1148

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56

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PHARMACIA CNS RSD
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
4/3	99	Placebo	Female		2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. HORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	28	28	28	28	28	28	28	28	28	28	28	28	28
100		Imipramine	Female		2	2	2	2	2	2	2	2	2	2	2	2	2	2
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. HORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	26	26	26	26	26	26	26	26	26	26	26	26	26	26
101		Imipramine	Male		3	3	3	3	3	3	3	3	3	3	3	3	3	3
				01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. HORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2

1149

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57

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42						
4/3	101	Imipramine	Male	09. AGITATION	0	0	0	1	1	1	0	0	0	0	0	0	0	0						
				10. ANXIETY PSYCHIC	3	3	3	2	2	1	1	1	1	1	1	1	1	1	1	1				
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				14. GENITAL SYMPTOMS	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				22. Total score	27	27	27	29	23	11	9	6	3	1	1	1	1	1	1	1	1			
				4/4	109	Reboxetine	Female	01. DEPRESSED MOOD	2	2	2	1	1	1	0	0	0	0	0	0	0	0		
								02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
								04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
09. AGITATION	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1				
10. ANXIETY PSYCHIC	3	3	3					2	2	1	1	1	1	1	1	1	1	1	1	1				
11. ANXIETY SOMATIC	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2				
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1				
13. SOMATIC GENERAL	1	1	1					2	2	2	2	2	2	2	2	2	2	2	2	2				
14. GENITAL SYMPTOMS	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0				
15. HYPOCHONDRIASIS	0	0	0					1	1	1	1	1	1	1	1	1	1	1	1	1				
16. LOSS OF WEIGHT	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2				
17. INSIGHT	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0				
18. DIURNAL VARIATION	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0				
19. DEPERSONALIZATION	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0				
20. PARANOID	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0				
22. Total score	27	25	18					13	8	6	3	1	1	1	1	1	1	1	1	1				
110	110	Imipramine	Male	01. DEPRESSED MOOD	2	3	2	2	2	2	1	1	1	1	1	1	1	1						
				02. GUILT	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1					
				03. SUICIDE	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	4	4	4	3	3	2	2	2	2	2	2	2	2	2	2					
				08. RETARDATION	2	3	2	2	2	2	2	2	2	2	2	2	2	2	2					
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				10. ANXIETY PSYCHIC	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2					
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					

1130

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58

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/4	110	Imipramine	Male	13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOIA 21. OBSESSIVE/COMPULSIVE 22. Total score	2 0 0 2 0 0 0 0 0 26	1 0 0 2 0 0 0 0 0 27	1 0 0 0 0 0 0 0 0 18	2 0 0 0 0 0 0 0 0 20	1 0 0 0 0 0 0 0 0 12	1 0 0 0 0 0 0 0 0 9	1 0 0 0 0 0 0 0 0 8
	111	Imipramine	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOIA 21. OBSESSIVE/COMPULSIVE 22. Total score	2 1 1 2 1 2 4 3 0 3 2 2 0 0 2 2 0 0 0 28	2 2 1 2 1 2 2 4 3 2 1 2 2 0 0 0 0 0 25	2 1 1 1 1 2 2 2 1 1 1 2 2 0 0 0 0 0 23	1 0 0 1 1 1 3 2 1 1 1 1 1 1 1 1 1 1 1 14	1 0 0 1 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 10	1 0 0 1 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 8	1 0 0 1 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 6
	112	Placebo	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT	2 0 1 2 2 2 4 1 1 2 2 2 0 0 2 2 0 0 0 2	2 1 1 2 2 2 4 1 1 2 2 2 0 0 2 2 0 0 0 25	2 0 0 1 1 1 3 2 1 1 1 1 1 1 1 1 1 1 1 23	2 0 0 1 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 14	1 0 0 1 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 10	1 0 0 1 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 8	1 0 0 1 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 6

1151

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59

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/4	112	Placebo	Male			0	0	0	0	0	0	0
				17. INSIGHT		0	0	0	0	0	0	0
				18. DIURNAL VARIATION		0	0	0	0	0	0	0
				19. DEPERSONALIZATION		0	0	0	0	0	0	0
				20. PARANOID		0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE		0	0	0	0	0	0	0
				22. Total score		25	22	15	13	11	9	16
	113	Reboxetine	Male			3	2	2	2	1	1	0
				01. DEPRESSED MOOD		3	2	2	2	1	1	0
				02. GUILT		2	2	1	1	1	1	0
				03. SUICIDE		2	2	1	1	0	0	0
				04. INSOMNIA EARLY		2	1	1	1	1	1	1
				05. INSOMNIA MIDDLE		2	2	2	1	1	1	0
				06. INSOMNIA LATE		2	2	2	1	1	1	0
				07. WORK AND ACTIVITIES		4	4	4	4	3	2	1
				08. RETARDATION		2	2	2	1	1	1	0
				09. AGITATION		0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC		2	2	2	2	1	1	1
				11. ANXIETY SOMATIC		1	2	2	1	1	1	0
				12. SOMATIC GASTROINTESTINAL		2	2	2	1	1	1	1
				13. SOMATIC GENERAL		1	1	2	1	1	1	1
				14. GENITAL SYMPTOMS		0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS		0	0	0	0	0	0	0
				16. LOSS OF WEIGHT		1	0	2	0	2	0	0
				17. INSIGHT		0	0	0	0	0	0	0
				18. DIURNAL VARIATION		0	0	0	0	0	0	0
				19. DEPERSONALIZATION		0	0	0	0	0	0	0
				20. PARANOID		0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE		0	0	0	0	0	0	0
				22. Total score		26	25	18	16	12	7	4
	114	Placebo	Female			3	3	2	2	1	1	1
				01. DEPRESSED MOOD		3	3	2	2	1	1	1
				02. GUILT		2	2	1	1	0	0	0
				03. SUICIDE		1	1	1	0	0	0	0
				04. INSOMNIA EARLY		2	2	1	1	1	1	1
				05. INSOMNIA MIDDLE		1	0	1	0	0	0	0
				06. INSOMNIA LATE		1	2	1	1	0	0	0
				07. WORK AND ACTIVITIES		3	3	3	3	2	2	1
				08. RETARDATION		2	2	2	1	1	1	1
				09. AGITATION		0	1	0	0	0	0	0
				10. ANXIETY PSYCHIC		2	3	2	2	2	2	1
				11. ANXIETY SOMATIC		3	3	3	2	2	2	2
				12. SOMATIC GASTROINTESTINAL		2	2	2	2	1	1	0
				13. SOMATIC GENERAL		2	2	2	2	1	1	0
				14. GENITAL SYMPTOMS		1	1	1	0	0	0	0
				15. HYPOCHONDRIASIS		1	1	1	0	0	0	0
				16. LOSS OF WEIGHT		1	0	0	0	0	0	0
				17. INSIGHT		0	0	0	0	0	0	0
				18. DIURNAL VARIATION		1	1	0	0	0	0	0
				19. DEPERSONALIZATION		0	0	0	0	0	0	0
				20. PARANOID		0	0	0	0	0	0	0

1152

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60

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PHARMACIA CNS RED
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
4/4	114	Placebo	Female	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	29	25	17	13	11	9	9							
	175	Inipramine	Female	01. DEPRESSED MOOD	3	3	2	1	1	1	1	1	1	1	1	1	0	0	0
				02. GUILT	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				03. SUICIDE	1	2	1	1	1	1	1	1	1	1	1	1	1	1	0
				04. INSOMNIA EARLY	2	2	1	1	1	1	1	1	1	1	1	1	1	1	0
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				06. INSOMNIA LATE	1	2	2	1	1	1	1	1	1	1	1	1	1	1	0
				07. WORK AND ACTIVITIES	3	4	4	3	2	2	2	2	2	2	2	2	2	2	1
				08. RETARDATION	2	2	2	1	1	1	1	1	1	1	1	1	1	1	0
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				11. ANXIETY SOMATIC	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1
				12. SOMATIC GASTROINTESTINAL	1	2	1	2	1	1	1	1	1	1	1	1	1	1	0
				13. SOMATIC GENERAL	2	2	1	2	1	1	1	1	1	1	1	1	1	1	0
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	25	26	21	18	13	10	10	6	3						
	176	Placebo	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	3
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				04. INSOMNIA EARLY	2	1	0	0	0	0	0	0	0	0	0	0	0	0	4
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
				07. WORK AND ACTIVITIES	4	4	3	2	2	2	2	2	2	2	2	2	2	2	4
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	24	24	20	16	16	16	16	16	16	16	16	16	16	16	27

1153

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61

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
4/4	177	Imipramine	Female	HAMILTON DEPRESSION RATING SCALE		2	2	2	2	2	2	2	2	2	2	2	2	2
				01. DEPRESSED MOOD		1	1	1	1	1	1	1	1	1	1	1	1	1
				02. GUILT		1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE		2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY		1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE		1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE		2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES		3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION		1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION		0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC		2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC		3	3	3	3	3	3	3	3	3	3	3	3	3
				12. SOMATIC GASTROINTESTINAL		2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL		2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS		0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDELIASIS		3	3	3	3	3	3	3	3	3	3	3	3	3
				16. LOSS OF WEIGHT		2	2	2	2	2	2	2	2	2	2	2	2	2
				17. INSIGHT		0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION		0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION		0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID		0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE		0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score		27	26	23	25									
						2	2	2	2	2	2	2	2	2	2	2	2	2
				01. DEPRESSED MOOD		1	1	1	1	1	1	1	1	1	1	1	1	1
				02. GUILT		1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE		2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY		1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE		1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE		2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES		4	4	4	4	4	4	4	4	4	4	4	4	4
				08. RETARDATION		2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION		0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC		3	3	3	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC		2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL		2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL		0	0	0	0	0	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS		0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDELIASIS		1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT		0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT		0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION		0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION		0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID		0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE		0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score		26	24	17	10	8	5	5	5	5	5	5	5	5
						3	2	2	2	2	2	3	3	3	3	3	3	3
				01. DEPRESSED MOOD		2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT		3	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE		2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY		2	2	2	2	2	2	2	2	2	2	2	2	2

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62

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
4/4	179	Placebo	Female	05. INSOMNIA MIDDLE	1	2	1	1	1	1	1	1				
				06. INSOMNIA LATE	2	2	2	1	2	2	2					
				07. WORK AND ACTIVITIES	4	4	3	2	4	4	4					
				08. RETARDATION	2	1	1	1	3	3	3					
				09. AGITATION	0	0	0	0	0	0	0					
				10. ANXIETY PSYCHIC	2	2	2	1	3	3	3					
				11. ANXIETY SOMATIC	1	1	1	1	0	0	0					
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2					
				13. SOMATIC GENERAL	2	2	2	2	2	2	2					
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	1	0	1	0	1	1	1					
				17. INSIGHT	1	0	0	0	0	0	0					
				18. DIURNAL VARIATION	1	1	1	1	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	30	25	23	18	31	31	31					
				180	180	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	1	1	1	1	0
								02. GUILT	2	2	1	1	0	0	0	
								03. SUICIDE	2	1	1	1	0	0	0	
								04. INSOMNIA EARLY	2	2	2	1	0	1	1	
05. INSOMNIA MIDDLE	1	1	1					0	0	0	0					
06. INSOMNIA LATE	2	2	1					1	1	0	0					
07. WORK AND ACTIVITIES	4	4	3					2	2	1	1					
08. RETARDATION	1	2	2					1	0	0	0					
09. AGITATION	0	0	0					0	0	0	0					
10. ANXIETY PSYCHIC	2	2	2					1	1	1	0					
11. ANXIETY SOMATIC	1	1	1					1	1	1	0					
12. SOMATIC GASTROINTESTINAL	2	2	2					1	1	1	0					
13. SOMATIC GENERAL	2	2	1					1	1	1	0					
14. GENITAL SYMPTOMS	1	1	1					1	1	1	1					
15. HYPOCHONDRIASIS	0	0	0					0	0	0	0					
16. LOSS OF WEIGHT	1	0	0					0	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	0	1	0					0	0	0	0					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	26	26	20					13	10	6	3					
5/1	127	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	1	3	1	1				
				02. GUILT	1	2	1	1	2	2	1					
				03. SUICIDE	0	0	0	0	0	0	0					
				04. INSOMNIA EARLY	1	2	0	1	1	2	0					
				05. INSOMNIA MIDDLE	1	1	2	1	1	1	1					
				06. INSOMNIA LATE	1	1	1	1	1	0	1					
				07. WORK AND ACTIVITIES	4	4	3	2	2	3	2					
				08. RETARDATION	3	3	2	2	2	2	2					

1155

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63

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
5/1	127	Reboxetine	Male	09. ACITATION	1	0	0	0	0	1	2	2	2	0	0	1	1	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	30	31	21	21	21	21	21	21	21	21	20	18	18	20	20
12B		Reboxetine	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. ACITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	36	33	13	13	13	14	14	14	14	13	13	13	15	15	15
129		Placebo	Male	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. ACITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

1156

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64

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PHARMACIA CNS R&D
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre Patient Treatment	Sex	Hamilton depression rating scale														
		Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
5/1 129	Male	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
		1	1	1	1	1	1	1	1	1	1	1	1	1	0	0
		1	1	1	1	1	1	1	1	1	1	1	1	1	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		25	25	23	23	14	14	10	6	9	9	6	6	9	19	
		22.Total score														
130	Male	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
		1	1	0	1	1	1	1	1	1	1	1	1	1	1	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		1	1	0	1	0	1	0	2	1	0	2	1	0	0	0
		4	4	3	3	3	3	3	3	3	3	3	3	3	3	3
		3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
		3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
		3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
		3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
		33	33	22	22	16	16	22	11	6	6	11	6	12	12	
		22.Total score														
131	Female	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
		3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
		1	1	0	1	0	1	2	1	0	0	0	0	0	0	0
		1	1	0	0	1	0	1	1	0	0	0	0	0	0	0
		1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
5/1	131	Imipramine	Female	17. INSIGHT	0	0	1	1	1	0	0	0				
				18. DIURNAL VARIATION	1	1	1	1	2	1	1	0				
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0				
				20. PARANOID	0	0	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	2	1	1	0				
				22. Total score	26	26	19	18	22	10	6	3				
				132	132	Imipramine	Male	01. DEPRESSED MOOD	3	3	0	0	0	0	0	0
								02. GUILT	1	1	0	0	0	0	0	0
								03. SUICIDE	3	3	0	0	0	0	0	0
								04. INSOMNIA EARLY	2	2	0	0	0	0	0	0
								05. INSOMNIA MIDDLE	1	1	1	1	0	0	0	0
								06. INSOMNIA LATE	1	1	1	1	0	0	0	0
								07. WORK AND ACTIVITIES	2	2	0	0	0	0	0	0
08. RETARDATION	2	2	0					0	0	0	0	0				
09. AGITATION	1	1	0					0	0	0	0	0				
10. ANXIETY PSYCHIC	3	3	0					0	0	0	0	0				
11. ANXIETY SOMATIC	2	2	0					0	0	0	0	0				
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	0	0	0				
13. SOMATIC GENERAL	2	2	0					0	1	0	0	0				
14. CENTRAL SYMPTOMS	0	0	0	0	0	0	0	0								
15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0								
17. INSIGHT	0	0	0	0	0	0	0	0								
18. DIURNAL VARIATION	1	1	1	1	0	0	0	0								
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0								
20. PARANOID	0	0	0	0	0	0	0	0								
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0								
22. Total score	24	24	2	1	0	0	0	0								
5/2	121	Imipramine	Female	01. DEPRESSED MOOD	4	4	3	2	2	1	1	3				
				02. GUILT	3	3	2	2	0	1	1					
				03. SUICIDE	3	3	3	2	0	1	2					
				04. INSOMNIA EARLY	2	2	2	1	1	1	1					
				05. INSOMNIA MIDDLE	0	0	1	0	0	0	0					
				06. INSOMNIA LATE	2	2	1	2	0	0	0					
				07. WORK AND ACTIVITIES	4	4	3	4	2	3	3					
				08. RETARDATION	2	2	2	2	2	1	2					
				09. AGITATION	2	2	2	2	2	1	1					
				10. ANXIETY PSYCHIC	4	4	3	3	2	2	3					
				11. ANXIETY SOMATIC	2	2	2	2	2	2	3					
				12. SOMATIC GASTROINTESTINAL	1	1	2	2	1	2	2					
				13. SOMATIC GENERAL	1	1	1	1	0	1	1					
14. CENTRAL SYMPTOMS	3	3	3	3	2	2	3									
15. HYPOCHONDRIASIS	2	2	0	1	1	0	2									
16. LOSS OF WEIGHT	0	0	0	0	0	0	0									
17. INSIGHT	1	1	1	1	0	0	1									
18. DIURNAL VARIATION	0	0	0	0	0	0	0									
19. DEPERSONALIZATION	0	0	0	0	0	0	0									
20. PARANOID	0	0	0	0	0	0	0									

1158

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PHARMACIA CMS R&D
 REBOXYTINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
5/2	121	Imipramine	Female	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	37	34	33	34	16	19	20	28							
	125	Reboxetine	Male	01.DEPRESSED MOOD	3	2	3	0	0	0	0	0	0	0	0	0	0	0	0
				02.GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				03.SUICIDE	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	1	0	1	0	1	1	2							
				05.INSOMNIA MIDDLE	0	0	0	0	1	1	0	1							
				06.INSOMNIA LATE	0	1	2	1	1	1	0	1							
				07.WORK AND ACTIVITIES	4	4	4	1	1	1	1	1							
				08.RETARDATION	3	2	1	1	0	0	0	0							
				09.AGITATION	0	1	3	0	0	1	1	1							
				10.ANXIETY PSYCHIC	2	2	3	0	1	1	1	1							
				11.ANXIETY SOMATIC	1	1	2	0	1	1	1	1							
				12.SOMATIC GASTROINTESTINAL	1	1	2	0	1	0	0	1							
				13.SOMATIC GENERAL	2	2	2	1	1	1	0	1							
				14.GENITAL SYMPTOMS	2	1	1	1	1	0	0	1							
				15.HYPOCHONDRIASIS	3	3	3	1	0	0	1	0							
				16.LOSS OF WEIGHT	0	1	0	0	0	0	0	0							
				17.INSIGHT	0	1	0	0	0	0	0	0							
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0							
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0							
				20.PARANOID	0	0	0	0	0	0	0	0							
				21.OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0	0							
				22.Total score	23	24	27	7	8	6	5	8							
5/3	133	Placebo	Male	01.DEPRESSED MOOD	3	3	3	3	3	3	3	3							
				02.GUILT	2	2	2	2	2	2	2	2							
				03.SUICIDE	1	1	1	1	1	1	1	1							
				04.INSOMNIA EARLY	2	1	1	1	1	2	2	2							
				05.INSOMNIA MIDDLE	2	2	2	2	2	2	2	2							
				06.INSOMNIA LATE	2	2	2	2	2	2	2	2							
				07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	3							
				08.RETARDATION	2	2	2	2	2	2	2	2							
				09.AGITATION	0	0	0	0	0	0	0	0							
				10.ANXIETY PSYCHIC	3	3	3	3	3	3	3	3							
				11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2							
				12.SOMATIC GASTROINTESTINAL	2	2	2	1	1	1	1	1							
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1							
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1							
				15.HYPOCHONDRIASIS	1	1	1	1	1	1	1	1							
				16.LOSS OF WEIGHT	2	0	0	0	0	0	0	0							
				17.INSIGHT	0	0	0	0	0	0	0	0							
				18.DIURNAL VARIATION	2	2	2	2	2	2	2	2							
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0							
				20.PARANOID	0	0	0	0	0	0	0	0							
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1							
				22.Total score	32	29	31	31	31	31	31	36							

1159

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67

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
5/3	134	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	1	2	0	0	0
				02. GUILT	2	2	1	0	2	0	0	0
				03. SUICIDE	2	1	1	0	1	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	0	0
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	0
				07. WORK AND ACTIVITIES	2	2	2	1	2	0	0	0
				08. RETARDATION	2	2	2	0	1	0	0	0
				09. AGITATION	2	2	2	1	2	0	0	1
				10. ANXIETY PSYCHIC	3	3	3	1	2	0	0	1
				11. ANXIETY SOMATIC	2	2	2	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	0	0	0	0	0
				14. GENITAL SYMPTOMS	2	2	1	0	0	0	0	0
				15. HYPOCHONDRIASIS	2	2	1	0	0	0	0	0
				16. LOSS OF HEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	1	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	33	32	28	10	20	6	2	2
135		Imipramine	Female	01. DEPRESSED MOOD	3	3	1	0	0	0	2	3
				02. GUILT	2	1	0	0	0	0	1	2
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	2	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	1	0	0	0	2	2
				06. INSOMNIA LATE	1	2	1	0	0	0	0	1
				07. WORK AND ACTIVITIES	2	2	1	1	1	2	3	3
				08. RETARDATION	1	1	0	0	0	0	1	1
				09. AGITATION	0	1	0	0	0	0	0	1
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	2	2
				11. ANXIETY SOMATIC	2	1	0	0	0	0	0	2
				12. SOMATIC GASTROINTESTINAL	2	2	0	1	1	1	0	2
				13. SOMATIC GENERAL	2	1	0	0	0	0	0	2
				14. GENITAL SYMPTOMS	2	2	1	0	0	0	0	1
				15. HYPOCHONDRIASIS	1	1	0	0	0	0	0	2
				16. LOSS OF HEIGHT	2	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	1	0	0	0	0	0	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	25	24	8	4	4	8	14	26
136		Imipramine	Female	01. DEPRESSED MOOD	3	3	2	0	0	0	0	0
				02. GUILT	2	2	1	0	0	0	0	0
				03. SUICIDE	1	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	1	0

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PHARMACIA CNS R6D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
S/3	136	Imipramine	Female	05. INSOMNIA MIDDLE	1	2	0	1	1	2	1				
				06. INSOMNIA LATE	2	2	0	0	0	0					
				07. WORK AND ACTIVITIES	3	3	2	1	0	1	0	0			
				08. RETARDATION	2	1	1	0	0	0	0	0			
				09. AGITATION	0	1	1	0	0	0	0	0			
				10. ANXIETY PSYCHIC	2	2	2	1	0	1	0	0			
				11. ANXIETY SOMATIC	2	3	3	1	0	0	0	0			
				12. SOMATIC GASTROINTESTINAL	1	1	2	0	0	0	0	0			
				13. SOMATIC GENERAL	2	2	2	1	0	1	0	0			
				14. GENITAL SYMPTOMS	1	2	2	0	0	0	0	0			
				15. HYPOCHONDRIASIS	3	2	2	0	0	0	0	0			
				16. LOSS OF WEIGHT	1	0	0	0	0	0	0	0			
				17. INSIGHT	1	1	0	0	0	0	0	0			
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0			
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0			
				20. PARANOID	0	0	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0			
				22. Total score	29	30	26	6	3	6	3	6	3	1	
				1161	137	Reboxetine	Female	01. DEPRESSED MOOD	3	3	1	0	0	0	0
								02. GUILT	2	2	1	0	0	0	0
								03. SUICIDE	1	1	0	0	0	0	0
								04. INSOMNIA EARLY	2	2	2	2	2	2	1
05. INSOMNIA MIDDLE	2	1	1					2	2	2	2	0			
06. INSOMNIA LATE	2	2	2					1	1	1	1	1			
07. WORK AND ACTIVITIES	3	3	2					1	0	0	0	0			
08. RETARDATION	0	3	3					1	0	0	0	0			
09. AGITATION	0	2	2					1	0	0	0	0			
10. ANXIETY PSYCHIC	2	2	2					1	1	1	1	1			
11. ANXIETY SOMATIC	2	2	2					1	0	0	0	0			
12. SOMATIC GASTROINTESTINAL	1	1	1					0	0	0	0	0			
13. SOMATIC GENERAL	2	2	2					1	1	1	1	1			
14. GENITAL SYMPTOMS	1	1	2					1	0	0	0	0			
15. HYPOCHONDRIASIS	2	2	2					1	0	0	0	0			
16. LOSS OF WEIGHT	0	0	0					0	0	0	0	0			
17. INSIGHT	0	0	0					0	0	0	0	0			
18. DIURNAL VARIATION	0	0	0					0	0	0	0	0			
19. DEPERSONALIZATION	0	0	0					0	0	0	0	0			
20. PARANOID	0	0	0					0	0	0	0	0			
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0	0			
22. Total score	30	31	21					9	7	7	4	4			
138	138	Placebo	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3				
				02. GUILT	2	2	2	2	2	2					
				03. SUICIDE	1	0	0	0	0	0					
				04. INSOMNIA EARLY	2	1	1	1	1	1					
				05. INSOMNIA MIDDLE	1	1	1	1	1	1					
				06. INSOMNIA LATE	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	3	3	3	3	3	3					
				08. RETARDATION	1	1	1	1	1	1					

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69

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
5/3	136	Placebo	Female		2	1	1	2	1	1	1	2	2	2	2	2	2	2
				09. ACITATION														
				10. ANXIETY PSYCHIC														
				11. ANXIETY SOMATIC														
				12. SOMATIC GASTROINTESTINAL														
				13. SOMATIC GENERAL														
				14. GENITAL SYMPTOMS														
				15. HYPOCHONDRIASIS														
				16. LOSS OF WEIGHT														
				17. INSIGHT														
				18. DIURNAL VARIATION														
				19. DEPERSONALIZATION														
				20. PARANOID														
				21. OBSESSIONAL/COMPULSIVE														
				22. Total score		30	28	28	28	28	28	28	28	28	28	28	28	28
6/1	151	Imipramine	Male		3	3	3	3	3	3	3	3	3	3	3	3	3	3
				01. DEPRESSED MOOD														
				02. GUILT														
				03. SUICIDE														
				04. INSOMNIA EARLY														
				05. INSOMNIA MIDDLE														
				06. INSOMNIA LATE														
				07. WORK AND ACTIVITIES														
				08. RETARDATION														
				09. ACITATION														
				10. ANXIETY PSYCHIC														
				11. ANXIETY SOMATIC														
				12. SOMATIC GASTROINTESTINAL														
				13. SOMATIC GENERAL														
				14. GENITAL SYMPTOMS														
				15. HYPOCHONDRIASIS														
				16. LOSS OF WEIGHT														
				17. INSIGHT														
				18. DIURNAL VARIATION														
				19. DEPERSONALIZATION														
				20. PARANOID														
				21. OBSESSIONAL/COMPULSIVE														
				22. Total score		26	26	22	22	22	22	22	22	22	22	22	22	22
152		Reboxetine	Female		3	3	3	3	3	3	3	3	3	3	3	3	3	3
				01. DEPRESSED MOOD														
				02. GUILT														
				03. SUICIDE														
				04. INSOMNIA EARLY														
				05. INSOMNIA MIDDLE														
				06. INSOMNIA LATE														
				07. WORK AND ACTIVITIES														
				08. RETARDATION														
				09. ACITATION														
				10. ANXIETY PSYCHIC														
				11. ANXIETY SOMATIC														
				12. SOMATIC GASTROINTESTINAL														

1162

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70

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42				
6/1	152	Reboxetine	Female	13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	1				
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				15. HYPOCHONDRIASIS	0	2	2	1	1	2	2	1	1	1	1	1	1	1	1	0	0	
				16. LOSS OF WEIGHT	2	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				18. DIURNAL VARIATION	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				22. Total score	26	26	21	20	17	18	14	14	13									
				153	Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	3	2	2	2	1	1	1	1	1	1	1	1
							02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
03. SUICIDE	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1			
04. INSOMNIA EARLY	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1			
05. INSOMNIA MIDDLE	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1			
06. INSOMNIA LATE	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1			
07. WORK AND ACTIVITIES	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2			
08. RETARDATION	3	3	3				3	2	2	2	2	2	2	2	2	2	2	2	2			
09. ACTIVATION	1	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0			
10. ANXIETY PSYCHIC	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0			
11. ANXIETY SOMATIC	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2			
12. SOMATIC GASTROINTESTINAL	3	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2			
13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1						
14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2						
15. HYPOCHONDRIASIS	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2						
16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1						
17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0						
18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0						
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0						
20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0						
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0						
22. Total score	26	23	21	16	15	14	14	13														
154	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
			02. GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
			03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
			04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
			06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
			07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
			08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
			09. ACTIVATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
			10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1							
14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2							
15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							

1163

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71

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
6/1	154	Imipramine	Female	17.INSIGHT	0	0										
				18.DIURNAL VARIATION	0	0										
				19.PERSONALIZATION	0	0										
				20.PARANOID	0	0										
				21.OBSESSIONAL/COMPULSIVE	0	0										
				22.Total score	23	23										
				155	155	Placebo	Male	01.DEPRESSED MOOD	4	4	4	4	3	3	3	3
								02.GUILT	1	1	1	1	1	1	2	
								03.SUICIDE	1	1	1	1	1	1	2	
								04.INSOMNIA EARLY	2	2	2	2	2	2	1	
								05.INSOMNIA MIDDLE	2	2	2	2	2	2	2	
								06.INSOMNIA LATE	2	2	2	2	2	2	2	
								07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	
08.RETARDATION	2	2	2					2	2	2	2					
09.AGITATION	2	2	2					2	2	2	1					
10.ANXIETY PSYCHIC	2	2	2					2	2	2	2					
11.ANXIETY SOMATIC	2	2	2					2	2	2	2					
12.SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1					
13.SOMATIC GENERAL	2	2	2					2	2	2	2					
14.GENITAL SYMPTOMS	2	2	2	2	2	2	2									
15.HYPOCHONDRIASIS	0	0	0	0	0	0	0									
16.LOSS OF WEIGHT	1	1	1	1	1	1	1									
17.INSIGHT	0	0	0	0	0	0	0									
18.DIURNAL VARIATION	0	0	0	0	0	0	0									
19.PERSONALIZATION	0	0	0	0	0	0	0									
20.PARANOID	0	0	0	0	0	0	0									
21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0									
22.Total score	30	30	27	27	23	23	26									
156	156	Placebo	Female	01.DEPRESSED MOOD	2	3	3	3	1	1	1	1				
				02.GUILT	1	1	1	1	0	0	0					
				03.SUICIDE	0	1	0	0	0	0	0					
				04.INSOMNIA EARLY	1	1	1	1	1	1	0					
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0					
				06.INSOMNIA LATE	0	0	0	0	0	0	0					
				07.WORK AND ACTIVITIES	3	3	3	3	2	2	1					
				08.RETARDATION	2	2	2	2	2	2	1					
				09.AGITATION	1	1	1	1	1	1	0					
				10.ANXIETY PSYCHIC	2	1	2	1	1	1	2					
				11.ANXIETY SOMATIC	2	1	2	1	1	1	1					
				12.SOMATIC GASTROINTESTINAL	2	2	1	1	1	1	0					
				13.SOMATIC GENERAL	1	1	1	1	1	1	0					
14.GENITAL SYMPTOMS	1	1	1	1	1	1	0									
15.HYPOCHONDRIASIS	2	2	2	2	0	1	1									
16.LOSS OF WEIGHT	2	2	2	2	0	0	0									
17.INSIGHT	0	0	0	0	0	0	0									
18.DIURNAL VARIATION	0	0	0	0	0	0	0									
19.PERSONALIZATION	0	0	0	0	0	0	0									
20.PARANOID	0	0	0	0	0	0	0									

1164

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72

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42		
6/1	156	Placebo	Female	21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	0	0	0	0	0	0	0	1		
				22. Total score	23	24	22	14	12	8	7	10									
6/2	157	Reboxetine	Male	01. DEPRESSED MOOD	3	2	2	2	1	1	1	1	1	1	1	1	1	1	1		
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				03. SUICIDE	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	1	1	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	2	1	0	2	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	1	1	1	2	2	1	1	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	2	3	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	29	29	27	19	18	17	16	14	14								
158	158	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	2	2	2	2	2	2	2	2	2	2	1		
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				04. INSOMNIA EARLY	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	
				05. INSOMNIA MIDDLE	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	
				06. INSOMNIA LATE	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				10. ANXIETY PSYCHIC	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				13. SOMATIC GENERAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				18. DIURNAL VARIATION	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				22. Total score	24	24	22	17	14	13	13	4									

1163

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74

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

Centre	Patient	Treatment	Sex	HAMILTON DEPRESSION RATING SCALE														
				Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day
6/2	161	Reboxetine	Female	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				24	23	24	24	19	21	21	21	21	21	21	21	21	21	21
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
				4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				3	3	3	3	3	3	3	3	3	3	3	3	3	3	3

1167

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75

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
6/2	169	Imipramine	Female		2	2	4	4	0	1	3	3	3					
				09. ACTIVATION	4	4	4	4	0	1	3	3	3					
				10. ANXIETY PSYCHIC	3	3	3	3	1	1	4	4	4					
				11. ANXIETY SOMATIC	2	2	2	2	1	1	2	2	2					
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	1	1	2	2	2					
				13. SOMATIC GENERAL	2	2	2	2	0	0	2	2	2					
				14. CERITAL SYMPTOMS	2	2	2	2	0	0	2	2	2					
				15. HYPOCHONDRIASIS	3	3	3	3	0	0	3	3	3					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	1					
				17. INSIGHT	1	1	1	1	0	0	1	1	2					
				18. DIURNAL VARIATION	1	1	1	1	0	0	1	1	2					
				19. DEPERSONALIZATION	1	1	1	1	0	0	1	1	2					
				20. PARANOID	2	2	2	2	0	0	2	2	2					
				21. OBSESSIONAL/COMPULSIVE	47	47	47	47	5	5	53	53	58					
				22. Total score														
170		Placebo	Male		4	4	4	4	2	2								
				01. DEPRESSED MOOD	4	4	4	4	2	2								
				02. GUILT	2	2	2	2	1	1								
				03. SUICIDE	2	2	2	2	1	1								
				04. INSOMNIA EARLY	2	2	2	2	1	1								
				05. INSOMNIA MIDDLE	2	2	2	2	0	0								
				06. INSOMNIA LATE	3	3	3	3	1	1								
				07. WORK AND ACTIVITIES	3	3	3	3	1	1								
				08. RETARDATION	2	2	2	2	1	1								
				09. AGITATION	4	4	4	4	1	1								
				10. ANXIETY PSYCHIC	3	3	3	3	1	1								
				11. ANXIETY SOMATIC	2	2	2	2	0	0								
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	1	1								
				13. SOMATIC GENERAL	2	2	2	2	0	0								
				14. CERITAL SYMPTOMS	3	3	3	3	0	0								
				15. HYPOCHONDRIASIS	3	3	3	3	0	0								
				16. LOSS OF WEIGHT	0	0	0	0	0	0								
				17. INSIGHT	2	2	2	2	1	1								
				18. DIURNAL VARIATION	2	2	2	2	1	1								
				19. DEPERSONALIZATION	3	3	3	3	1	1								
				20. PARANOID	2	2	2	2	0	0								
				21. OBSESSIONAL/COMPULSIVE	2	2	2	2	0	0								
				22. Total score	52	54	54	54	16	16								
171		Imipramine	Female		2	2	2	2	2	2	1	1	0	0	0	0	0	0
				01. DEPRESSED MOOD	2	2	2	2	2	2	1	1	0	0	0	0	0	0
				02. GUILT	3	3	3	3	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	1	0	0	0	1	1	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	1	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	1	2	2	2	1	1	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	4	2	2	2	2	2	1	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	3	2	2	0	0	0	0	0	0	0	0
				08. RETARDATION	3	3	3	3	2	2	1	1	0	0	0	0	0	0
				09. AGITATION	3	3	3	3	2	2	1	1	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	3	2	2	1	1	0	0	0	0	0	0
				11. ANXIETY SOMATIC	3	3	3	3	2	2	1	1	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	1	1	0	0	0	0	0	0

1168

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76

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PHARMACIA CNS R&D
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/2	171	Imipramine	Female	13.SOMATIC GENERAL	2	2	2	1	0	0	0	0
				14.GERITAL SYMPTOMS	2	2	2	2	0	0	0	0
				15.HYPOCHONDRIASIS	3	3	3	1	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	1	1	0	0	0	0	0
				20.PARANOID	2	2	2	1	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	1	0	0	0	0
				22.Total score	43	35	34	16	2	0	0	0
172		Reboxetine	Female	01.DEPRESSED MOOD	4	4	4	4	4	4	3	3
				02.GUILT	2	2	2	2	2	2	2	2
				03.SUICIDE	2	2	3	3	3	3	3	3
				04.INSOMNIA EARLY	2	2	2	2	2	2	2	2
				05.INSOMNIA MIDDLE	2	2	2	2	2	2	2	2
				06.INSOMNIA LATE	2	2	2	2	2	2	2	2
				07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	3
				08.RETARDATION	3	3	3	3	3	3	3	3
				09.AGITATION	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	2
				14.GERITAL SYMPTOMS	3	3	3	2	2	2	2	2
				15.HYPOCHONDRIASIS	3	3	3	2	2	2	2	2
				16.LOSS OF WEIGHT	3	3	3	3	1	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19.DEPERSONALIZATION	1	1	1	1	1	1	1	1
				20.PARANOID	0	0	1	1	1	1	1	1
				21.OBSESSIONAL/COMPULSIVE	1	1	1	2	2	2	2	2
				22.Total score	39	39	41	41	39	38	38	38
173		Placebo	Male	01.DEPRESSED MOOD	2	2	2	2	2	3	2	2
				02.GUILT	2	2	3	3	3	3	2	2
				03.SUICIDE	3	3	3	1	1	3	1	1
				04.INSOMNIA EARLY	1	1	1	2	2	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	2	2	2	0	0
				06.INSOMNIA LATE	2	2	2	2	2	2	0	0
				07.WORK AND ACTIVITIES	4	4	3	3	3	3	2	2
				08.RETARDATION	2	2	2	2	2	3	2	2
				09.AGITATION	2	2	2	2	2	1	1	1
				10.ANXIETY PSYCHIC	3	3	3	3	3	4	2	3
				11.ANXIETY SOMATIC	2	2	2	2	2	3	2	2
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	1	1
				13.SOMATIC GENERAL	2	2	2	2	2	2	1	1
				14.GERITAL SYMPTOMS	2	2	2	2	2	2	1	1
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	1	1
				16.LOSS OF WEIGHT	3	3	3	3	3	3	2	1

1169

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77

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/2	173	Placebo	Male	17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	1 1 1 2 2 41	0 1 1 2 2 40	0 1 1 2 2 38	0 1 1 2 2 39	0 1 1 2 2 39	0 0 0 2 2 43	0 0 0 2 2 25	0 1 1 1 2 27
174		Reboxetine	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. MORE AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. CENTRAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	4 2 3 2 2 2 3 2 4 4 2 2 2 2 2 2 2 2 2 2 46	4 2 3 2 2 2 4 4 1 2 2 2 2 2 2 2 2 2 2 2 44	1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 5	0 6	0 6	0 6	2 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 14	
6/3	163	Reboxetine	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. MORE AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. CENTRAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID	2 0 1 0 0 0 0 2 2 3 1 1 1 3 1 1 1 1 1 1 46	3 0 1 0 0 0 0 2 2 3 1 1 1 3 1 1 1 1 1 1 44	2 0 0 0 0 0 0 2 2 3 1 1 1 3 1 1 1 1 1 1 5	0 0 0 0 0 0 0 2 2 3 1 1 1 3 1 1 1 1 1 1 6	0 0 0 0 0 0 0 2 2 3 1 1 1 3 1 1 1 1 1 1 6	0 0 0 0 0 0 0 2 2 3 1 1 1 3 1 1 1 1 1 1 6	2 2 1 0 0 0 0 2 2 3 1 1 1 3 1 1 1 1 1 1 14	

1170

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78

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
6/3	163	Reboxetine	Male	21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	2		
				22.Total score	27	27	27	27	27	27	27	27	27	
6/3	164	Imipramine	Male	01.DEPRESSED MOOD	2	2	2	2	2	2	2	2		
				02.GUILT	0	0	0	1	1	1	1	0	0	
				03.SUICIDE	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	3	3	2	2	2	2	2	2
				08.RETARDATION	2	2	2	2	2	2	2	2	2	2
				09.AGITATION	1	1	1	2	1	2	2	2	2	1
				10.ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3
				11.ANXIETY SOMATIC	1	1	1	2	2	2	3	3	3	2
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2
				14.GENITAL SYMPTOMS	3	3	3	3	3	3	3	3	3	3
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0
				16.LOSS OF HEIGHT	1	1	1	0	0	0	0	0	0	0
				17.INSIGHT	2	2	2	2	2	2	2	2	2	2
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	2	2	2
				22.Total score	26	26	27	19	19	20	17	15	14	14
6/3	165	Imipramine	Female	01.DEPRESSED MOOD	2	2	2	2	2	2	2	1		
				02.GUILT	2	2	2	0	0	0	1	2	1	
				03.SUICIDE	0	0	0	0	0	0	0	0	0	
				04.INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	
				06.INSOMNIA LATE	2	2	2	1	1	0	0	0	0	
				07.WORK AND ACTIVITIES	3	2	2	2	2	2	2	2	2	
				08.RETARDATION	1	2	2	2	2	2	2	1	0	
				09.AGITATION	2	2	2	2	2	2	2	2	2	
				10.ANXIETY PSYCHIC	2	3	3	3	3	3	3	3	3	
				11.ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0	0	
				13.SOMATIC GENERAL	0	0	0	0	0	0	0	0	0	
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	
				16.LOSS OF HEIGHT	2	2	2	0	0	0	0	0	0	
				17.INSIGHT	1	1	1	1	1	2	2	2	2	
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	
				20.PARANOID	0	0	0	0	0	0	0	0	0	
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	
				22.Total score	27	30	22	22	21	19	19	15		

1171

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79

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	166	Reboxetine	Female	01. DEPRESSED MOOD	2	3	2					
				02. GUILT	1	1	1					
				03. SUICIDE	0	0	3					
				04. INSOMNIA EARLY	0	0	2					
				05. INSOMNIA MIDDLE	0	0	2					
				06. INSOMNIA LATE	0	0	0					
				07. WORK AND ACTIVITIES	3	4	4					
				08. RETARDATION	2	2	3					
				09. AGITATION	2	2	2					
				10. ANXIETY PSYCHIC	3	3	3					
				11. ANXIETY SOMATIC	2	2	2					
				12. SOMATIC GASTROINTESTINAL	1	1	1					
				13. SOMATIC GENERAL	1	2	2					
				14. GENITAL SYMPTOMS	2	2	2					
				15. HYPOCHONDRIASIS	2	3	3					
				16. LOSS OF WEIGHT	0	0	0					
				17. INSIGHT	0	0	0					
				18. DIURNAL VARIATION	2	2	2					
				19. DEPERSONALIZATION	0	0	0					
				20. PARANOID	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	1	1	1					
				22. Total score	24	28	35					
	167	Placebo	Female	01. DEPRESSED MOOD	2	2	2	2	2	1	1	1
				02. GUILT	2	2	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	2	2	2	2	2	1	1	1
				08. RETARDATION	1	0	2	1	2	1	0	0
				09. AGITATION	2	2	1	1	2	1	0	0
				10. ANXIETY PSYCHIC	3	3	3	3	1	2	2	2
				11. ANXIETY SOMATIC	1	2	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	1	1
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	2	2	2	1	0	0
				19. DEPERSONALIZATION	2	2	0	0	2	1	0	1
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	2	2	1	2	1	1	1	1
				22. Total score	25	23	19	17	17	12	9	11
	168	Placebo	Female	01. DEPRESSED MOOD	2	3	2	2	2	2	2	2
				02. GUILT	2	2	0	0	1	2	2	2
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	0	1	0	1	1	2	2

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PHARMACIA CNS R&D
 RESOMETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
6/3	168	Placebo	Female	05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	0	2	1	1	0	1	1	1	1	1	1	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	1	1	2	2	2	1	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	3	3	3	3	3	3	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	1	1	0	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	2	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	2	2	2	2	1	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	2	2	2	2	2	1	1	1	1	1	1	1	1	1
				22. Total score	27	28	24	24	21	21	21	21	21	24	24	26		
505		Imipramine	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	2	2	2	2	2	2	2	2	2	2	2	2	2
				22. Total score	24	27	23	23	25	25	25	25	25	25	25	25	25	25
506		Placebo	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2

1173

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81

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
6/3	506	Placebo	Female	09. ACTIVATION	0	0	1	2	1	0	0	0				
				10. ANXIETY PSYCHIC	3	3	2	2	2	1	2	2				
				11. ANXIETY SOMATIC	2	2	3	2	2	1	2	2				
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0				
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1				
				14. GENITAL SYMPTOMS	2	2	2	2	2	1	2	1				
				15. HYPOCHONDRIASIS	2	2	3	2	2	1	1	2				
				16. LOSS OF WEIGHT	2	0	0	0	0	0	0	0				
				17. INSIGHT	0	0	0	0	0	0	0	0				
				18. DIURNAL VARIATION	2	2	1	0	2	0	1	0				
				19. DEPERSONALIZATION	1	1	0	0	0	0	0	0				
				20. PARANOID	0	0	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	0	1	1	1				
				22. Total score	26	25	23	22	25	16	17	20				
				507	507	Imipramine	Female	01. DEPRESSED MOOD	2	2	2	2	2	1	1	1
								02. GUILT	0	0	0	0	0	0	0	
								03. SUICIDE	0	0	0	0	0	0	0	
								04. INSOMNIA EARLY	0	0	0	0	0	0	0	
								05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	
								06. INSOMNIA LATE	1	1	0	0	0	0	0	
								07. WORK AND ACTIVITIES	2	2	2	1	1	0	0	
								08. RETARDATION	1	1	1	1	1	1	0	
09. AGITATION	2	2	1					2	0	1	0					
10. ANXIETY PSYCHIC	3	3	2					3	2	1	1					
11. ANXIETY SOMATIC	2	2	3					2	1	1	1					
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	0	0					
13. SOMATIC GENERAL	1	1	1					1	1	1	1					
14. GENITAL SYMPTOMS	2	2	2					2	1	1	1					
15. HYPOCHONDRIASIS	0	0	0					0	0	0	0					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	2	2	2					1	0	0	0					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	1	1	1					1	1	1	1					
22. Total score	23	23	20					18	11	10	6	4				
508	508	Reboxetine	Female	01. DEPRESSED MOOD	2	2	1	2	2	2	1	1				
				02. GUILT	1	1	0	1	1	1	1					
				03. SUICIDE	0	0	0	0	0	0	0					
				04. INSOMNIA EARLY	1	1	2	0	1	0	1					
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0					
				06. INSOMNIA LATE	1	1	0	0	1	0	0					
				07. WORK AND ACTIVITIES	2	2	2	2	2	1	1					
				08. RETARDATION	2	2	2	2	1	1	1					
				09. AGITATION	1	1	1	0	0	0	0					
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	1					
				11. ANXIETY SOMATIC	1	1	2	0	0	0	0					
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
6/3	508	Reboxetine	Female	13. SOMATIC GENERAL	0	1	0	0	1	1	0	0	1	1	0	0	0	0
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	22	24	17	17	16	16	16	11	9					
	509	Placebo	Male	01. DEPRESSED MOOD	2	2	1	1	1	1	2	1	1	1	1	2	1	0
				02. GUILT	1	2	1	1	1	1	1	1	1	1	1	1	1	0
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	2	0	1	0	1	0	0	0	0	0	0	1
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	1
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0	0	0	1
				07. WORK AND ACTIVITIES	2	2	1	2	1	2	1	2	1	2	1	2	1	0
				08. RETARDATION	1	2	1	1	1	1	1	1	1	1	1	1	1	1
				09. ACITATION	1	2	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	3	2	2	1	2	2	2	1	2	2	1	1	1
				11. ANXIETY SOMATIC	3	2	2	1	2	1	2	1	0	1	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	0	1	0	0	1	1	1	0	1	0	1	1	1	1
				13. SOMATIC GENERAL	1	1	0	0	1	1	1	0	1	0	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	3	2	2	1	2	2	2	2	2	2	2	2	2	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	1	0	0	0	0	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	22	23	15	14	14	13	13	14	14	13	14	14	13	13
	510	Reboxetine	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	1	2	1	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. ACITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
 RESOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
6/3	510	Reboxetine	Female	17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				22. Total score	24	24	18	18	18	18	18	18	18	18	18	18	18	18	18
511		Imipramine	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				22. Total score	23	27	15	13	16	16	16	16	16	16	16	16	16	16	16
512		Placebo	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	512	Placebo	Female	21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1
				22.Total score	23	24	26					
513		Imipramine	Female	01.DEPRESSED MOOD	2	2	2	2	2	1	1	1
				02.GUILT	1	1	1	1	1	1	1	1
				03.SUICIDE	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	1	1	0	1	0	0
				06.INSOMNIA LATE	1	1	1	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	1	1	1	0	0	1
				08.RETARDATION	2	2	1	1	1	0	0	0
				09.AGITATION	2	2	2	1	2	2	1	1
				10.ANXIETY PSYCHIC	3	3	2	1	1	2	1	1
				11.ANXIETY SOMATIC	2	2	2	1	1	0	1	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	1	0	0	0	0
				15.HYPOCHONDRIASIS	3	3	2	1	1	1	1	1
				16.LOSS OF HEIGHT	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	1	1	1	1	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1
				22.Total score	25	25	19	13	12	10	9	7
7/02	181	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	4	3	2	2	2
				02.GUILT	1	1	1	1	1	1	1	1
				03.SUICIDE	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	2	1	1	1	1
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	2	2
				08.RETARDATION	1	1	1	1	1	1	0	0
				09.AGITATION	2	2	2	2	1	2	2	2
				10.ANXIETY PSYCHIC	4	4	4	4	3	3	3	3
				11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	2
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16.LOSS OF HEIGHT	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	1	1	1	0	0
				18.DIURNAL VARIATION	1	1	1	1	1	1	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22.Total score	23	23	23	24	20	19	17	17

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PHARMACIA CTS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
7/02	182	Placebo	Male	01. DEPRESSED MOOD	3	3	2	2	1	1	1	1	1	1	1	1	1	1
				02. GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	2	2	1	1	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	3	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	3	3	3	3	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	23	22	14	13	15	14	15	14	15	14	15	14	15
183		Imipramine	Male	01. DEPRESSED MOOD	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	24	24	20	22	22	23	23	23	23	23	23	23	23	23
184		Imipramine	Female	01. DEPRESSED MOOD	4	4	4	4	3	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2

1178

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86

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
7/02	184	Imipramine	Female	05. INSOMNIA MIDDLE	1	1	1	1	1	1	0	0				
				06. INSOMNIA LATE	2	2	1	1	1	0	0					
				07. WORK AND ACTIVITIES	3	3	2	1	1	1	0					
				08. RETARDATION	1	1	1	0	0	0	0					
				09. AGITATION	1	1	2	0	0	0	0					
				10. ANXIETY PSYCHIC	3	3	2	1	1	0	0					
				11. ANXIETY SOMATIC	1	1	1	1	2	1	0					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	2	1	0					
				13. SOMATIC GENERAL	1	1	1	1	1	1	1					
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1					
				15. HYPOCHONDRIASIS	2	2	2	2	1	1	1					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	1	0	1	1	1	1	0					
				19. DEPERSONALIZATION	1	1	1	1	1	1	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	26	26	26	22	12	12	6	3				
				7/02	185	Reboxetine	Male	01. DEPRESSED MOOD	1	1	2	2	1	1	2	1
								02. GUILT	2	2	2	1	1	1	1	
								03. SUICIDE	0	0	0	0	0	0	0	
								04. INSOMNIA EARLY	2	2	2	2	2	2	2	
05. INSOMNIA MIDDLE	2	2	2					2	2	2	2					
06. INSOMNIA LATE	1	1	1					1	1	1	1					
07. WORK AND ACTIVITIES	1	1	1					1	1	1	1					
08. RETARDATION	0	0	0					0	0	0	0					
09. AGITATION	1	1	1					1	1	1	1					
10. ANXIETY PSYCHIC	2	2	2					2	2	2	1					
11. ANXIETY SOMATIC	3	3	3					3	3	3	1					
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1					
13. SOMATIC GENERAL	2	2	2					2	2	2	1					
14. GENITAL SYMPTOMS	1	1	1					1	1	1	1					
15. HYPOCHONDRIASIS	1	1	1					1	1	1	1					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	1	1	1					1	1	1	1					
18. DIURNAL VARIATION	0	0	0					0	0	0	0					
19. DEPERSONALIZATION	1	1	1					1	1	1	1					
20. PARANOID	1	1	1					1	1	1	1					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	23	23	26					23	23	21	11	0				
7/02	186	Placebo	Male	01. DEPRESSED MOOD	2	2	1	1	1	1	1	0				
				02. GUILT	1	1	1	1	1	1	1					
				03. SUICIDE	2	2	2	1	0	0	0					
				04. INSOMNIA EARLY	2	2	2	2	1	1	1					
				05. INSOMNIA MIDDLE	2	2	2	1	1	1	0					
				06. INSOMNIA LATE	2	2	2	2	2	2	0					
				07. WORK AND ACTIVITIES	1	1	1	1	1	1	0					
				08. RETARDATION	1	1	1	1	1	1	0					

1179

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87

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
7/02	186	Placebo	Male	09. AGITATION	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	2	1	1	1	1	1	1	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	23	21	19	16	15	14	14	14	14	14	14	14	14	14
535		Placebo	Male	01. DEPRESSED MOOD	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	27	27	27	29	30	29	27	27	27	27	27	27	27	27	27
536		Reboxetine	Female	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

1180

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89

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
7/03	188	Placebo	Male	17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	23	23	23	23	23	10	14	14	14	14	14	14	14
189		Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	2	2	1	1	1	1	1	1	1	1
				02. GUILT	1	1	1	1	1	1	0	0	0	0	0	0	0	0
				03. SUICIDE	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	2	2	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				08. RETARDATION	3	3	3	3	1	1	0	0	0	0	0	0	0	0
				09. AGITATION	0	1	1	1	0	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	1	1	1	1	1	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	1	1	1	1	1	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	25	25	26	26	13	13	6	6	6	6	6	6	6	6
190		Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	3	3	3	3	1	1	1	1	1	1	1	1
				08. RETARDATION	1	1	2	2	2	2	0	0	0	0	0	0	0	0
				09. AGITATION	0	0	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	1	1	1	1	1	1	1	1	1	1	1	1	1	1

1182

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90

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
7/03	190	Reboxetine	Male	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	22	23	21	21	12	11	11	11	11	11	11	11	11	11	11
	191	Imipramine	Female	01. DEPRESSED MOOD	3	4	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	0	0	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	2	1	1	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	2	3	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	1	2	0	0	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	1	1	0	0	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	1	0	0	0	0	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	27	31	16	16	10	15	15	15	15	15	15	15	15	15	15
	192	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	23	23	14	14	14	14	14	14	14	14	14	14	14	14

9550082

91

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day
7/03	523	Reboxetine	Female		3	3	3	3	2	1	1	1
				01. DEPRESSED MOOD	3	3	3	3	2	1	1	1
				02. GUILT	3	3	3	3	0	0	0	0
				03. SUICIDE	1	1	1	1	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	2	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	3	3	2	2	2	2
				08. RETARDATION	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	1	1	1	1	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	28	29	29	29	17	16	16	16
524		Placebo	Female		3	3	3	3	2	1	1	1
				01. DEPRESSED MOOD	3	3	3	3	2	1	1	1
				02. GUILT	2	2	2	2	1	1	1	1
				03. SUICIDE	1	1	1	1	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	0	0	0
				05. INSOMNIA MIDDLE	1	1	1	1	1	0	0	0
				06. INSOMNIA LATE	2	2	2	2	1	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	3	2	1	1	1
				08. RETARDATION	1	1	1	1	1	0	0	0
				09. AGITATION	2	2	2	2	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	3	3	3	3	1	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	0	0	0
				19. DEPERSONALIZATION	1	1	1	1	1	0	0	0
				20. PARANOID	0	0	0	0	1	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	29	29	30	26	16	8	8	8
525		Placebo	Female		3	3	3	3	2	1	1	1
				01. DEPRESSED MOOD	3	3	3	3	1	1	1	1
				02. GUILT	3	3	3	3	1	0	0	0
				03. SUICIDE	1	1	1	1	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	0	0	0

1184

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92

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PHARMACIA CNS RD
 KEROMETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day				
7/03	525	Placebo	Female	05. INSOMNIA MIDDLE	2	2	2	1	1	0	0	0				
				06. INSOMNIA LATE	2	2	2	0	0	0	0					
				07. WORK AND ACTIVITIES	3	3	3	2	1	1	1					
				08. RETARDATION	2	2	2	2	1	1	1					
				09. AGITATION	1	1	1	1	1	1	0					
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1					
				11. ANXIETY SOMATIC	2	2	2	2	1	1	1					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0					
				13. SOMATIC GENERAL	1	1	1	1	1	0	0					
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1					
				15. HYPOCHONDRIASIS	2	2	2	2	2	0	0					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	0	0	0	0	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	28	28	28	19	14	5	4					
				11/05	526	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	1	1
								02. GUILT	3	3	3	2	2	2	0	
								03. SUICIDE	0	0	0	0	0	0	0	
								04. INSOMNIA EARLY	2	2	2	2	2	2	1	
05. INSOMNIA MIDDLE	2	2	2					2	2	2	1					
06. INSOMNIA LATE	2	2	2					2	2	2	1					
07. WORK AND ACTIVITIES	3	3	3					2	2	2	1					
08. RETARDATION	3	3	3					3	3	3	1					
09. AGITATION	1	1	1					1	1	1	1					
10. ANXIETY PSYCHIC	1	1	1					1	1	1	1					
11. ANXIETY SOMATIC	1	1	1					1	1	1	1					
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1					
13. SOMATIC GENERAL	1	1	1					1	1	1	1					
14. GENITAL SYMPTOMS	1	1	1					1	1	1	1					
15. HYPOCHONDRIASIS	2	2	2					2	2	2	0					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	0	0	0					0	0	0	0					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	26	26	26					23	23	12	4					
7/03	527	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	2	2	2	2				
				02. GUILT	2	2	2	2	1	1	1					
				03. SUICIDE	1	1	1	1	0	0	0					
				04. INSOMNIA EARLY	1	1	1	1	1	1	1					
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1					
				06. INSOMNIA LATE	1	1	1	1	1	1	1					
				07. WORK AND ACTIVITIES	3	3	3	3	2	2	2					
				08. RETARDATION	1	1	1	1	0	0	0					

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93

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day
7/03	527	Imipramine	Female	09. AGITATION	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	3	3	3	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	1	1	1	1	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	0	0	0	0
				19. DEPERSONALIZATION	1	1	1	1	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	27	27	27	27	16	16	16	16
528		Imipramine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	3	3
				02. GUILT	2	2	1	1	1	1	2	2
				03. SUICIDE	1	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	2	1	0	0	0	0	1	1
				07. WORK AND ACTIVITIES	3	2	2	2	2	2	2	2
				08. RETARDATION	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	0	0	0	0	0	0
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	25	23	17	17	17	17	20	20
7/04	193	Placebo	Female	01. DEPRESSED MOOD	3	3	3	3	1	1	0	0
				02. GUILT	2	2	2	2	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	2	1	1	0	0
				06. INSOMNIA LATE	2	2	2	2	1	1	0	0
				07. WORK AND ACTIVITIES	2	2	2	2	1	1	0	0
				08. RETARDATION	2	2	2	2	1	1	0	0
				09. AGITATION	2	2	2	2	1	1	0	0
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1	1
				11. ANXIETY SOMATIC	3	3	3	3	2	2	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	1	1	0	0

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
7/04	193	Placebo	Female	13. SOMATIC GENERAL	1	1	1	1	0	0	0			
				14. GENITAL SYMPTOMS	0	0	0	0	0	0				
				15. HYPOCHONDRIASIS	0	0	0	0	0	0				
				16. LOSS OF WEIGHT	2	2	2	1	1	1				
				17. INSIGHT	1	1	1	1	0	0				
				18. DIURNAL VARIATION	0	0	0	0	0	0				
				19. DEPERSONALIZATION	0	0	0	0	0	0				
				20. PARANOID	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0				
				22. Total score	28	28	28	17	8	5				
				194	Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	2	1	1	1
							02. GUILT	3	3	3	2	1	0	
03. SUICIDE	0	0	0				0	0	0					
04. INSOMNIA EARLY	2	2	2				1	1	0					
05. INSOMNIA MIDDLE	2	2	2				1	1	0					
06. INSOMNIA LATE	2	2	2				2	1	1					
07. WORK AND ACTIVITIES	2	2	2				2	1	1					
08. RESTATION	2	2	2				2	1	1					
09. ACTIVATION	3	3	3				2	1	1					
10. ANXIETY PSYCHIC	2	2	2				1	1	1					
11. ANXIETY SOMATIC	0	0	0				0	0	0					
12. SOMATIC GASTROINTESTINAL	2	2	2				2	1	1					
195	Placebo	Female	01. DEPRESSED MOOD	3	3	3	1	1	1	1				
			02. GUILT	3	3	3	1	1	1					
			03. SUICIDE	0	0	0	0	0	0					
			04. INSOMNIA EARLY	2	2	2	1	0	0					
			05. INSOMNIA MIDDLE	2	2	2	2	1	1					
			06. INSOMNIA LATE	2	2	2	2	1	1					
			07. WORK AND ACTIVITIES	2	2	2	2	1	1					
			08. RESTATION	2	2	2	2	1	1					
			09. ACTIVATION	2	2	2	2	1	1					
			10. ANXIETY PSYCHIC	2	2	2	2	1	1					
			11. ANXIETY SOMATIC	2	2	2	2	1	1					
			12. SOMATIC GASTROINTESTINAL	2	2	2	2	1	1					
13. SOMATIC GENERAL	1	1	1	1	1	1								
14. GENITAL SYMPTOMS	0	0	0	0	0	0								
15. HYPOCHONDRIASIS	0	0	0	0	0	0								
16. LOSS OF WEIGHT	3	3	3	2	1	1								
17. INSIGHT	2	2	2	2	1	1								
18. DIURNAL VARIATION	0	0	0	0	0	0								
19. DEPERSONALIZATION	2	2	2	2	1	1								
20. PARANOID	0	0	0	0	0	0								
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0								
22. Total score	32	32	32	20	12	7								

1187

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95

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/04	195	Placebo	Female		2	2	2	2	1	1	1	1
				17.INSIGHT	1	1	1	1	0	0	0	0
				16.DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22.Total score	28	28	28	28	16	8	8	7
196		Reboxetine	Female		3	3	3	3	2	1	1	1
				01.DEPRESSED MOOD	3	3	3	3	2	1	1	1
				02.GUILT	0	0	0	0	0	0	0	0
				03.SUICIDE	1	1	1	1	1	1	1	1
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1
				06.INSOMNIA LATE	2	2	2	2	1	1	1	1
				07.WORK AND ACTIVITIES	2	2	2	2	1	1	1	1
				08.RETARDATION	2	2	2	2	1	1	1	1
				09.AGITATION	2	2	2	2	1	1	1	1
				10.ANXIETY PSYCHIC	2	2	2	2	1	1	1	1
				11.ANXIETY SOMATIC	2	2	2	2	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17.INSIGHT	2	2	2	2	1	1	1	1
				18.DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22.Total score	26	26	26	26	19	14	7	6
197		Imipramine	Male		3	3	3	3	3	3	3	3
				01.DEPRESSED MOOD	3	3	3	3	3	3	3	3
				02.GUILT	0	0	0	0	0	0	0	0
				03.SUICIDE	1	1	1	1	2	2	2	2
				04.INSOMNIA EARLY	1	1	1	1	2	2	2	2
				05.INSOMNIA MIDDLE	2	2	2	2	2	2	2	2
				06.INSOMNIA LATE	2	2	2	2	2	2	2	2
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	2	2
				08.RETARDATION	2	2	2	2	2	2	2	2
				09.AGITATION	2	2	2	2	2	2	2	2
				10.ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	1	1	1	1	2	2	2	2
				17.INSIGHT	1	1	1	1	1	1	1	1
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0

1188

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96

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PHARMACIA CNS R&D

REBEXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/04	197	Imipramine	Male	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	27	27	28	28	28	28	28	27
198		Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	2	2	2	1
				02. GUILT	2	2	2	2	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	2	2	1	1	1	0
				06. INSOMNIA LATE	2	2	2	2	1	1	1	0
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	1
				08. RETARDATION	2	2	2	2	2	2	2	1
				09. AGITATION	2	2	2	2	2	2	2	1
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	1
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	0
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	2	2	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	27	27	27	27	14	10	9	5
199		Imipramine	Male	01. DEPRESSED MOOD	3	3	3	3	3	2	2	2
				02. GUILT	3	3	3	3	3	2	2	1
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	2	2	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	1
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	1
				08. RETARDATION	3	3	3	3	3	2	2	1
				09. AGITATION	2	2	2	2	2	2	2	1
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	0
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	1	1	1	1	0	0	0	0
				17. INSIGHT	2	2	2	2	2	2	2	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	29	29	29	28	27	19	16	15

1189

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97

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
7/04	200	Placebo	Male	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				09. AGITATION	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	28	28	28	27	25	23	22	22	22	22	22	22	22
201		Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	28	28	28	29	22	21	17	13	13	13	13	13	13
202		Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/04	202	Reboxetine	Male		1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3
				08. RETARDATION	3	3	3	3	3	3	3	3
				09. AGITATION	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF HEIGHT	1	1	1	1	1	1	1	1
				17. INSIGHT	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1
				20. PARANOIA	0	0	0	0	0	0	0	0
				21. OBSESSIVE/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	29	29	29	29	25	25	19	17
203		Placebo	Female		3	3	3	3	3	3	3	3
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2
				02. GUILT	0	0	0	0	0	0	0	0
				03. SUICIDE	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3
				08. RETARDATION	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF HEIGHT	1	1	1	1	1	1	1	1
				17. INSIGHT	2	2	2	2	2	2	2	2
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOIA	0	0	0	0	0	0	0	0
				21. OBSESSIVE/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	27	27	28	28	27	24	21	19
204		Imipramine	Female		2	2	2	2	2	2	2	1
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	1
				02. GUILT	0	0	0	0	0	0	0	0
				03. SUICIDE	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	1

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42							
7/04	204	Imipramine	Female	09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2						
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				17. INSIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				22. Total score	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26	26			
				7/05	205	Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		
								02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
								04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
								07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
								08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
09. AGITATION	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
10. ANXIETY PSYCHIC	3	3	3					3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
11. ANXIETY SOMATIC	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
13. SOMATIC GENERAL	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
14. GENITAL SYMPTOMS	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
15. HYPOCHONDRIASIS	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
16. LOSS OF WEIGHT	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
17. INSIGHT	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
18. DIURNAL VARIATION	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
19. DEPERSONALIZATION	1	1	1					1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
20. PARANOID	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
22. Total score	30	33	34					34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	33			
206	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3						
			02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/05	206	Imipramine	Female	13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	1 1 2 3 1 1 0 0 0 30	1 1 2 0 1 1 0 0 0 26	1 1 0 0 1 0 0 0 0 21	1 1 0 0 1 0 0 0 0 16	1 1 0 0 1 0 0 0 0 16	1 1 0 0 1 0 0 0 0 15	
207		Imipramine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	2 1 0 2 2 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 26	2 1 0 2 2 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 24	2 1 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 20	2 1 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 16	2 1 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 14	2 1 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 15	
208		Reboxetine	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT	2 2 0 2 2 2 2 2 2 2 2 1 1 1 1 1 1 1 1 1 26	2 2 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 24	2 2 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 20	2 2 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 16	2 2 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 14	2 2 0 1 1 1 2 2 2 2 2 1 1 1 1 1 1 1 1 1 15	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
7/05	208	Reboxetine	Male	17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	29	23	19	13	11	9	9	9	9	9	9	9	9
209		Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	26	26	28	28	28	28	29	30	31	31	31	31	31	31
210		Reboxetine	Male	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0

1194

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102

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	7	14	21	28	35	Day 42
7/05	210	Reboxetine	Male	21. OBSESSIONAL/COMPULSIVE 22. Total score	0	0	0	0	0	0	0	0
					24	24	20	13	11	8	9	8
541		Reboxetine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3	3	2	1	1	1	1	1
					2	2	2	1	1	1	1	1
					1	1	1	0	0	0	0	0
					2	2	1	1	0	0	0	0
					2	2	2	1	1	0	0	0
					3	3	2	1	1	1	1	1
					3	2	2	1	1	1	1	1
					2	2	2	2	1	1	1	1
					2	2	2	2	1	1	1	1
					2	2	2	2	1	1	1	1
					4	4	3	2	2	2	2	2
					3	3	3	2	2	2	2	2
					2	2	2	2	2	2	2	2
					4	4	3	3	2	2	2	2
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					3	3	3	3	2	2	2	2
					3	3	3	3	2	2	2	2
					2	2	2	2	2	2	2	2
					1	1	1	1	1	1	1	1
					2	2	2	2	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					3	3	3	3	2	2	2	2
					3	3	3	3	2	2	2	2
					0	0	0	0	0	0	0	0
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					2	2	2	2	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0
					29	30	24	15	10	7	7	6
542		Imipramine	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3	3	3	3	3	3	2	2
					2	2	2	2	2	2	2	2
					0	0	0	0	0	0	0	0
					2	2	2	1	1	1	1	1
					2	2	1	1	1	1	1	1
					2	2	2	1	1	1	1	1
					4	4	3	2	2	2	2	2
					3	3	3	2	2	2	2	2
					2	2	2	2	2	2	2	2
					4	4	3	3	2	2	2	2
					2	2	2	2	2	2	2	2
					2	2	2	2	2	2	2	2
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					3	3	3	3	2	2	2	2
					3	3	3	3	2	2	2	2
					2	2	2	2	2	2	2	2
					1	1	1	1	1	1	1	1
					2	2	2	2	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					1	1	1	1	1	1	1	1
					0	0	0	0	0	0	0	0
					0	0	0	0	0	0	0	0
					1	1	1	1	1	1	1	1
					38	37	35	29	24	24	23	21

1195

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103

PHARMACIA CNS RED
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42	
7/05	543	Imipramine	Male	01. DEPRESSED MOOD	3	3	2	2	1	1	1	1	1	1	1	1	1	1	1	1
				02. GUILT	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	23	23	19	14	12	9	9	9	9	9	9	9	9	9	9	9
544		Placebo	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	33	33	31	32	32	32	32	32	32	32	32	32	32	32	32	33
545		Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2

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104

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day
7/05	545	Placebo	Male	05. INSOMNIA MIDDLE	2	2	2	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3
				08. RETARDATION	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	3	3	3	3	3	3	3	3
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	2	2	2	2	2	2	2	2
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	36	36	34	34	34	34	34	35
546	Reboxetine	Female		01. DEPRESSED MOOD	3	3	2	2	1	1	1	1
				02. GUILT	2	2	2	1	1	1	1	1
				03. SUICIDE	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	2
				08. RETARDATION	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	2	2	2	2	2	2
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	26	27	24	19	15	12	13	12
7/07	529	Placebo	Female	01. DEPRESSED MOOD	4	3	3	3	2	2	2	2
				02. GUILT	1	2	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	1	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2
				08. RETARDATION	1	1	1	0	0	0	0	1

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105

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
7/07	529	Placebo	Female		1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	3	2	2	2	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	2	2	2	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	3	2	3	3	3	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	0	1	1	1	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	24	27	27	22	22	20	20	20	20	20	20	20	19
530		Imipramine	Female		3	3	3	3	3	3	3	3	3	3	3	3	3	3
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				07. WORK AND ACTIVITIES	0	1	1	1	1	1	1	1	1	1	1	1	1	1
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	0	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	0	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	26	27	25	27	25	27	25	27	25	27	25	27	25	27
531		Reboxetine	Female		3	3	3	3	3	3	3	3	3	3	3	3	3	3
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	0	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	0	0	0	0	0	0	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
7/07	531	Reboxetine	Female	13. SOMATIC GENERAL	2	2	2	2	2	2	2				
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1				
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0				
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0				
				17. INSIGHT	0	0	0	0	0	0	0				
				18. DIURNAL VARIATION	1	1	1	1	1	1	1				
				19. DEPERSONALIZATION	0	0	0	0	0	0	0				
				20. PARANOID	0	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0				
				22. Total score	26	25	28	21	20	25	18	20			
				532	Imipramine	Female	01. DEPRESSED MOOD	2	3	2	2	2	2	2	2
							02. GUILT	1	1	1	1	1	1	1	
03. SUICIDE	1	1	1				1	1	1	1					
04. INSOMNIA EARLY	2	2	2				2	2	2	2					
05. INSOMNIA MIDDLE	2	2	2				2	2	2	2					
06. INSOMNIA LATE	2	2	2				2	2	2	2					
07. WORK AND ACTIVITIES	2	2	2				2	2	2	2					
08. RETARDATION	1	1	1				1	1	1	1					
09. AGITATION	2	2	2				2	2	2	2					
10. ANXIETY PSYCHIC	2	2	2				2	2	2	2					
11. ANXIETY SOMATIC	2	3	3				2	2	2	2					
12. SOMATIC GASTROINTESTINAL	1	1	1				1	1	1	1					
533	Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3				
			02. GUILT	2	2	2	2	2	2	2					
			03. SUICIDE	1	2	2	2	2	2	2					
			04. INSOMNIA EARLY	2	2	2	2	2	2	2					
			05. INSOMNIA MIDDLE	2	2	2	2	2	2	2					
			06. INSOMNIA LATE	2	2	2	2	2	2	2					
			07. WORK AND ACTIVITIES	2	2	2	2	2	2	2					
			08. RETARDATION	1	1	1	1	1	1	1					
			09. AGITATION	2	2	2	2	2	2	2					
			10. ANXIETY PSYCHIC	3	3	3	3	3	3	3					
			11. ANXIETY SOMATIC	2	2	2	2	2	2	2					
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1					
13. SOMATIC GENERAL	2	2	2	2	2	2	2								
14. GENITAL SYMPTOMS	2	2	2	2	2	2	2								
15. HYPOCHONDRIASIS	1	2	2	2	2	2	2								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0								
17. INSIGHT	0	0	0	0	0	0	0								
18. DIURNAL VARIATION	1	1	1	1	1	1	1								
19. DEPERSONALIZATION	0	0	0	0	0	0	0								
20. PARANOID	0	0	0	0	0	0	0								
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0								
22. Total score	26	30	28	26	22	21	16								

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
7/07	533	Reboxetine	Male		0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	29	30	28	29	28	25	24	21						
534		Placebo	Female		3	2	2	3	3	2	2	3	2	2	3	1	1	2
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	1	1	1
				02. GUILT	2	1	1	0	0	1	0	0	1	1	0	0	0	0
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. CENTRAL SYMPTOMS	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	30	27	28	26	23	24	20	18						
8	211	Reboxetine	Female		4	4	4	4	4	4	4	4	4	4	4	4	4	4
				01. DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. CENTRAL SYMPTOMS	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
 REDUXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient	Treatment	Sex	HAMILTON DEPRESSION RATING SCALE																			
				Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42				
8	211	Reboxetine	Female	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				22.Total score	27	27	28	28	29														
				212	Placebo	Female	01.DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4		
							02.GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
							03.SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							04.INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							06.INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
							08.RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							09.AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							10.ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
							11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							15.HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							16.LOSS OF HEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							17.INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							20.PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21.OBSESSIONAL/COMPULSIVE	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0				
22.Total score	24	24	24				24	23	21	24	24	24	24	24	24	24	24	24	24				
213	Imipramine	Male	01.DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4						
			02.GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			03.SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			04.INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			06.INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
			08.RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			09.AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			10.ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
			11.ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			15.HYPOCHONDRIASIS	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
			16.LOSS OF HEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			17.INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			20.PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			22.Total score	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27				

1201

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109

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42			
8	214	Reboxetine	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4			
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF HEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23
215	215	Placebo	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	2	1	1	1	1	1	1	1			
				02. GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				04. INSOMNIA EARLY	2	2	2	1	1	1	0	0	0	0	0	0	0	0	0	0	
				05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	
				06. INSOMNIA LATE	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	3	2	1	1	1	1	
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				09. AGITATION	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				12. SOMATIC GASTROINTESTINAL	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				16. LOSS OF HEIGHT	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				22. Total score	22	22	22	15	15	15	10	9	5	5	4	4	4	4	4	4	
216	216	Imipramine	Male	01. DEPRESSED MOOD	4	4	4	4	4	4	3	3	3	3	3	3	2				
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
8	216	Imipramine	Male	05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	0				
				06. INSOMNIA LATE	2	2	1	1	1	0	0	0				
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	3	3				
				08. RETARDATION	0	0	0	0	0	0	0	0				
				09. AGITATION	1	1	1	1	1	1	1	1				
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2				
				11. ANXIETY SOMATIC	1	1	1	1	1	1	0	0				
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1				
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1				
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1				
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2				
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0				
				17. INSIGHT	0	0	0	0	0	0	0	0				
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0				
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0				
				20. PARANOIA	0	0	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0				
				22. Total score	22	22	21	20	18	16	14	13				
				217	Reboxetine	Female	04. DEPRESSED MOOD	4	4	4	3	2	2	2	2	2
							02. GUILT	1	1	1	1	0	0	0	0	
							03. SUICIDE	0	0	0	0	0	0	0	0	
							04. INSOMNIA EARLY	1	1	0	0	0	0	0	0	
05. INSOMNIA MIDDLE	1	1	0				0	0	0	0	0					
06. INSOMNIA LATE	1	1	1				1	1	1	1	1					
07. WORK AND ACTIVITIES	4	4	3				3	2	1	1	1					
08. RETARDATION	0	0	0				0	0	0	0	0					
09. AGITATION	1	1	1				1	1	1	1	1					
10. ANXIETY PSYCHIC	1	1	1				1	1	1	1	1					
11. ANXIETY SOMATIC	1	1	1				1	0	0	0	0					
12. SOMATIC GASTROINTESTINAL	1	1	1				1	1	1	1	1					
13. SOMATIC GENERAL	1	1	1				1	1	1	1	1					
14. GENITAL SYMPTOMS	2	2	2				2	2	1	1	1					
15. HYPOCHONDRIASIS	0	0	0				0	0	0	0	0					
16. LOSS OF WEIGHT	1	1	0				0	0	0	0	0					
17. INSIGHT	1	1	1				1	1	1	1	1					
18. DIURNAL VARIATION	1	1	1				1	1	1	1	1					
19. DEPERSONALIZATION	0	0	0				0	0	0	0	0					
20. PARANOIA	0	0	0				0	0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0				0	0	0	0	0					
22. Total score	22	22	18				14	8	6	4	5					
218	Reboxetine	Female	04. DEPRESSED MOOD	4	4	4	4	4	3	3	3	3				
			02. GUILT	1	1	1	1	1	1	1	1					
			03. SUICIDE	0	0	0	0	0	0	0	0					
			04. INSOMNIA EARLY	1	1	1	1	1	1	1	1					
			05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0					
			06. INSOMNIA LATE	2	2	2	2	1	1	1	1					
			07. WORK AND ACTIVITIES	3	3	3	3	3	2	2	2					
			08. RETARDATION	0	0	0	0	0	0	0	0					

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111

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42							
8	218	Reboxetine	Female	09. AGITATION	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1						
				10. ANXIETY PSYCHIC	3	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				15. HYPOCHONDRIASIS	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
				22. Total score	23	24	22	22	24	19	14	11	11	11	11	11	11	11	11	11	11	11	11		
				219	Placebo	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4		
							02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
							03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
							04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
							08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
09. AGITATION	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
10. ANXIETY PSYCHIC	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
11. ANXIETY SOMATIC	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
12. SOMATIC GASTROINTESTINAL	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
220	Imipramine	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4						
			02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4					
			08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					

1204

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112

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
8	220	Imipramine	Female	13. SOMATIC GENERAL	1	1	1	1	1	1	1	1			
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1			
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1			
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0		
				17. INSIGHT	0	0	0	0	0	0	0	0	0		
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1		
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0		
				20. PARANOID	0	0	0	0	0	0	0	0	0		
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1		
				22. Total score	22	22	22	20	15	13	10				
				221	Imipramine	Male	01. DEPRESSED MOOD	4	4	4	4	3	2	1	1
							02. GUILT	1	1	1	1	0	0	0	
							03. SUICIDE	0	0	0	0	0	0	0	
04. INSOMNIA EARLY	1	1	1				1	0	0	0					
05. INSOMNIA MIDDLE	1	1	1				1	0	0	0					
06. INSOMNIA LATE	0	1	1				1	1	1	1					
07. WORK AND ACTIVITIES	4	4	4				4	3	3	2					
08. RETARDATION	0	0	0				0	0	0	0					
09. AGITATION	1	1	1				1	1	1	1					
10. ANXIETY PSYCHIC	2	2	2				2	1	1	1					
11. ANXIETY SOMATIC	0	0	0				0	0	0	0					
12. SOMATIC GASTROINTESTINAL	0	0	0				0	0	0	0					
13. SOMATIC GENERAL	1	1	1				1	1	1	1					
14. GENITAL SYMPTOMS	1	1	1	1	1	1	1								
15. HYPOCHONDRIASIS	2	2	2	2	2	1	1								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0								
17. INSIGHT	1	1	1	1	1	1	1								
18. DIURNAL VARIATION	1	1	1	1	1	1	1								
19. DEPERSONALIZATION	0	0	0	0	0	0	0								
20. PARANOID	1	1	1	1	1	1	1								
21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1								
22. Total score	22	22	21	19	12	11	8								
222	Placebo	Female	01. DEPRESSED MOOD	4	4	2	2	1	1	2	2				
			02. GUILT	1	1	1	1	0	0	0					
			03. SUICIDE	0	0	0	0	0	0	0					
			04. INSOMNIA EARLY	1	1	1	1	0	0	1					
			05. INSOMNIA MIDDLE	1	1	1	1	0	0	1					
			06. INSOMNIA LATE	1	1	1	1	0	0	1					
			07. WORK AND ACTIVITIES	4	4	3	3	2	0	0					
			08. RETARDATION	0	0	0	0	0	0	0					
			09. AGITATION	1	1	1	1	1	1	1					
			10. ANXIETY PSYCHIC	2	2	1	1	0	0	0					
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1					
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1					
			13. SOMATIC GENERAL	1	1	1	1	1	1	1					
14. GENITAL SYMPTOMS	1	1	1	1	1	1	1								
15. HYPOCHONDRIASIS	2	2	1	1	1	1	1								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0								

1205

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113

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PHARMACIA CNS R&D
 RESOMETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42								
8	222	Placebo	Female	17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
				18. DIURNAL VARIATION	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				22. Total score	22	22	13	9	5	5	3	6	6	6	6	6	6	6	6	6	6	6				
				223	Imipramine	Female	01. DEPRESSED MOOD	4	4	4	4	3	3	3	3	2	2	2	2	2	2	2	2	2		
							02. GUILT	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
							03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
05. INSOMNIA MIDDLE	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
06. INSOMNIA LATE	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
07. WORK AND ACTIVITIES	4	4	4				4	4	4	3	3	3	2	2	2	2	2	2	2	2	2	2				
08. RETARDATION	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
09. AGITATION	2	1	2				1	2	1	2	1	2	1	2	1	2	1	2	1	2	1	2				
10. ANXIETY PSYCHIC	1	2	2				2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
11. ANXIETY SOMATIC	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1							
12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1							
13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1							
14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1							
15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2							
16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1							
17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0							
22. Total score	24	24	24	18	14	14	12	9	9	9	9	9	9	9	9	9	9	9	9							
224	Placebo	Female	01. DEPRESSED MOOD	4	4	4	4	3	3	3	3	2	2	2	2	2	2	2	2	2						
			02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2					
			08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			09. AGITATION	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
11. ANXIETY SOMATIC	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0								
17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0								
20. PARANOID	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1								

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114

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42		
8	224	Placebo	Female	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				22. Total score	24	23	20	17	16	15	12	10									
8	225	Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2		
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				14. CENTRAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	24	25	23	23	20	15	12									
8	226	Reboxetine	Male	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4		
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				14. CENTRAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				15. HYPOCHONDRIASIS	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				22. Total score	25	25	25	23	23	22	22	22									

1207

9550082

115

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

Centre	Patient Treatment	Sex	Hamilton depression rating scale	HAMILTON DEPRESSION RATING SCALE										
				Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
8	Reboxetine	Male	01. DEPRESSED MOOD	4	4	4	3	3	3	3	3	3	3	
			02. GUILT	1	1	1	1	1	1	1	1	1	1	
			04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0	0
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1
			06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1
			07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3
			08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0
			09. AGITATION	1	1	1	1	1	1	1	1	1	1	1
			10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2
			11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1
			13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1
			14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1
			15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2
			16. LOSS OF HEIGHT	0	0	0	0	0	0	0	0	0	0	0
			17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1
			18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1
			19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0
			20. PARANOID	0	0	0	0	0	0	0	0	0	0	0
			21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1
			22. Total score	24	25	23	22	21	19	18	17			
			228	Imipramine	Male	01. DEPRESSED MOOD	3	4	4					
02. GUILT	1	1				1								
03. SUICIDE	0	0				0								
04. INSOMNIA EARLY	1	1				1								
05. INSOMNIA MIDDLE	1	1				1								
06. INSOMNIA LATE	1	2				2								
07. WORK AND ACTIVITIES	3	3				3								
08. RETARDATION	0	0				0								
09. AGITATION	1	1				2								
10. ANXIETY PSYCHIC	1	2				2								
11. ANXIETY SOMATIC	1	1				1								
12. SOMATIC GASTROINTESTINAL	1	1				1								
13. SOMATIC GENERAL	1	1				1								
14. GENITAL SYMPTOMS	1	1				1								
15. HYPOCHONDRIASIS	2	2				2								
16. LOSS OF HEIGHT	1	0				0								
17. INSIGHT	1	1				1								
18. DIURNAL VARIATION	1	1				1								
19. DEPERSONALIZATION	0	0				0								
20. PARANOID	1	1				1								
21. OBSESSIONAL/COMPULSIVE	0	0				0								
22. Total score	22	24				25								
229	Imipramine	Female	01. DEPRESSED MOOD	4	4	4	3	3	3	3	3	2		
			02. GUILT	2	2	2	1	1	1	1	1	1		
			03. SUICIDE	0	0	0	0	0	0	0	0	0		
			04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1		

1208

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116

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day
8	229	Female	05.INSOMNIA MIDDLE 06.INSOMNIA LATE 07.WORK AND ACTIVITIES 08.RETARDATION 09.AGITATION 10.ANXIETY PSYCHIC 11.ANXIETY SOMATIC 12.SOMATIC GASTROINTESTINAL 13.SOMATIC GENERAL 14.GENITAL SYMPTOMS 15.HYPOCHONDRIASIS 16.LOSS OF HEIGHT 17.INSIGHT 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2
				3	3	3	3	3	3	3	3
				0	0	0	0	0	0	0	0
				2	2	2	2	2	2	2	2
				2	2	2	2	2	2	2	2
				1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2
				0	0	0	0	0	0	0	0
				1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2
				0	0	0	0	0	0	0	0
				1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2
				0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0
				25	25	25	20	19	18	18	15
230	Reboxetine	Female	01.DEPRESSED MOOD 02.GUILT 03.SUICIDE 04.INSOMNIA EARLY 05.INSOMNIA MIDDLE 06.INSOMNIA LATE 07.WORK AND ACTIVITIES 08.RETARDATION 09.AGITATION 10.ANXIETY PSYCHIC 11.ANXIETY SOMATIC 12.SOMATIC GASTROINTESTINAL 13.SOMATIC GENERAL 14.GENITAL SYMPTOMS 15.HYPOCHONDRIASIS 16.LOSS OF HEIGHT 17.INSIGHT 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	4	4	4	4	4	3	3	2
				1	1	1	1	1	1	1	1
				0	0	0	0	0	0	0	0
				2	2	2	2	2	2	2	2
				1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2
				4	4	4	4	4	4	4	3
				0	0	0	0	0	0	0	0
				2	2	2	2	2	2	2	2
				1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2
				0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0
				0	0	0	0	0	0	0	0
				26	26	25	24	22	20	19	18
231	Imipramine	Male	01.DEPRESSED MOOD 02.GUILT 03.SUICIDE 04.INSOMNIA EARLY 05.INSOMNIA MIDDLE 06.INSOMNIA LATE 07.WORK AND ACTIVITIES 08.RETARDATION	4	4	4	3	3	2	2	2
				1	1	1	1	1	1	1	1
				0	0	0	0	0	0	0	0
				1	1	1	1	1	1	1	1
				1	1	1	1	1	1	1	1
				2	2	2	2	2	2	2	2
				3	3	3	3	3	2	2	2
				0	0	0	0	0	0	0	0

1209

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117

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
8	231	Imipramine	Male	09. ACITATION	1	1	1	1	1	0	0	0				
				10. ANXIETY PSYCHIC	2	2	2	2	1	1	1					
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0					
				13. SOMATIC GENERAL	1	1	1	1	1	1	1					
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1					
				15. HYPOCHONDRIASIS	2	2	2	2	1	1	1					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					
				17. INSIGHT	1	1	0	0	0	0	0					
				18. DIURNAL VARIATION	1	1	1	1	1	1	1					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	23	23	22	19	16	13	12					
				232	Reboxetine	Male	01. DEPRESSED MOOD	4	4	4	3	3	3	2	2	2
							02. GUILT	1	1	1	1	1	1	1		
							03. SUICIDE	0	0	0	0	0	0	0		
							04. INSOMNIA EARLY	2	2	1	1	1	1	1		
							05. INSOMNIA MIDDLE	1	1	1	1	1	1	1		
							06. INSOMNIA LATE	1	1	1	1	1	1	1		
							07. WORK AND ACTIVITIES	3	3	3	3	3	2	2		
							08. RETARDATION	0	0	0	0	0	0	0		
09. AGITATION	1	1	1				1	1	1	1						
10. ANXIETY PSYCHIC	2	2	2				2	1	1	1						
11. ANXIETY SOMATIC	1	1	1				1	1	1	1						
12. SOMATIC GASTROINTESTINAL	1	1	1				1	1	1	0						
13. SOMATIC GENERAL	1	1	1				1	1	1	1						
14. GENITAL SYMPTOMS	2	2	2				2	1	1	1						
15. HYPOCHONDRIASIS	1	1	1				1	1	1	1						
16. LOSS OF WEIGHT	0	0	0				0	0	0	0						
17. INSIGHT	1	1	1				1	1	1	1						
18. DIURNAL VARIATION	1	1	1				1	1	1	1						
19. DEPERSONALIZATION	0	0	0				0	0	0	0						
20. PARANOID	0	0	0				0	0	0	0						
21. OBSESSIONAL/COMPULSIVE	1	1	1				1	1	1	1						
22. Total score	24	24	23				19	18	15	12						
233	Placebo	Female	01. DEPRESSED MOOD	4	4	4	4	4	3	3	2	2				
			02. GUILT	1	1	1	1	1	1	1						
			03. SUICIDE	0	0	0	0	0	0	0						
			04. INSOMNIA EARLY	2	2	2	2	1	1	1						
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1						
			06. INSOMNIA LATE	1	1	1	1	1	1	1						
			07. WORK AND ACTIVITIES	3	3	3	3	3	3	2						
			08. RETARDATION	0	0	0	0	0	0	0						
			09. AGITATION	2	2	2	2	2	1	1						
			10. ANXIETY PSYCHIC	1	1	1	1	1	1	1						
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1						
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0						

1210

9550082

118

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
8	233	Placebo	Female	13. SOMATIC GENERAL	1	1	1	1	1	1	1	1				
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1					
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					
				17. INSIGHT	1	1	1	1	1	1	1					
				18. DIURNAL VARIATION	1	1	1	1	1	1	1					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1					
				22. Total score	25	25	25	25	22	17	16	12				
				234	234	Placebo	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	3
								02. GUILT	1	1	1	1	1	1	1	
								03. SUICIDE	0	0	0	0	0	0	0	
04. INSOMNIA EARLY	1	1	1					1	1	1	1					
05. INSOMNIA MIDDLE	1	1	1					1	1	1	1					
06. INSOMNIA LATE	1	1	1					1	1	1	1					
07. WORK AND ACTIVITIES	3	3	3					3	3	3	3					
08. RETARDATION	0	0	0					0	0	0	0					
09. AGITATION	2	2	2					2	2	2	2					
10. ANXIETY PSYCHIC	1	1	1					1	1	1	1					
11. ANXIETY SOMATIC	1	1	1					1	1	1	1					
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1					
13. SOMATIC GENERAL	1	1	1					1	1	1	1					
14. GENITAL SYMPTOMS	1	1	1	1	1	1	1									
15. HYPOCHONDRIASIS	2	2	2	2	2	2	2									
16. LOSS OF WEIGHT	0	0	0	0	0	0	0									
17. INSIGHT	1	1	1	1	1	1	1									
18. DIURNAL VARIATION	1	1	1	1	1	1	1									
19. DEPERSONALIZATION	0	0	0	0	0	0	0									
20. PARANOID	0	0	0	0	0	0	0									
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0									
22. Total score	24	24	23	22	20	20	18	17								
8/A	235	Placebo	Female	01. DEPRESSED MOOD	3	2	2	2	2	2	2	2				
				02. GUILT	2	2	1	1	1	1	1					
				03. SUICIDE	1	1	1	1	0	0	0					
				04. INSOMNIA EARLY	1	2	2	2	2	2	2					
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1					
				06. INSOMNIA LATE	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	3	3	2	2	2	2	2					
				08. RETARDATION	1	1	1	1	1	1	1					
				09. AGITATION	2	2	1	1	1	1	1					
				10. ANXIETY PSYCHIC	2	3	2	1	1	1	1					
				11. ANXIETY SOMATIC	2	2	1	1	1	1	1					
				12. SOMATIC GASTROINTESTINAL	2	1	1	1	1	1	1					
				13. SOMATIC GENERAL	1	2	2	2	2	2	2					
14. GENITAL SYMPTOMS	1	2	1	1	1	1	1									
15. HYPOCHONDRIASIS	1	1	1	1	1	1	1									
16. LOSS OF WEIGHT	0	0	0	0	0	0	0									

1211

9550082

119

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
8/A	235	Placebo	Female	17.INSIGHT	2	2	2	2	1	1	1	1				
				16.DIURNAL VARIATION	1	2	1	1	1	1	1	1	1			
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0			
				20.PARANOID	1	1	1	0	0	0	0	0	0			
				21.OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	0	0			
				22.Total score	30	33	25	22	18	17	17	16				
				236	Placebo	Female	01.DEPRESSED MOOD	3	3	2	2	2	2	2	1	1
							02.GUILT	1	1	1	1	1	0	0	0	0
							03.SUICIDE	1	1	0	0	0	0	0	0	0
							04.INSOMNIA EARLY	2	2	2	2	2	1	1	1	1
							05.INSOMNIA MIDDLE	0	0	1	1	0	0	0	0	0
							06.INSOMNIA LATE	1	2	2	1	1	1	1	1	1
							07.WORK AND ACTIVITIES	3	3	2	2	1	1	1	1	1
08.RETARDATION	1	1	1				1	1	1	1	1	1				
09.AGITATION	2	2	1				1	1	1	1	0	0				
10.ANXIETY PSYCHIC	2	2	2				1	1	1	1	1	1				
11.ANXIETY SOMATIC	3	3	2				1	0	1	1	1	1				
12.SOMATIC GASTROINTESTINAL	1	1	1				0	0	1	0	0	0				
13.SOMATIC GENERAL	1	1	1				1	1	1	1	1	1				
14.CENTRAL SYMPTOMS	1	1	2	1	1	0	1	0	0							
15.HYPochondriasis	2	2	1	1	1	0	0	0	0							
16.LOSS OF WEIGHT	2	1	1	0	0	0	0	0	0							
17.INSIGHT	2	2	1	0	1	0	0	0	0							
18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0							
19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0							
20.PARANOID	1	1	1	0	0	0	0	0	0							
21.OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0	0	0							
22.Total score	30	30	24	16	13	11	9	8								
237	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	2	1	1	1				
			02.GUILT	3	2	2	1	1	0	0	0	0				
			03.SUICIDE	1	1	0	0	0	0	0	0	0				
			04.INSOMNIA EARLY	1	2	2	2	1	2	1	1	1				
			05.INSOMNIA MIDDLE	1	1	0	1	1	1	1	0	0				
			06.INSOMNIA LATE	2	2	2	1	1	1	1	1	1				
			07.WORK AND ACTIVITIES	3	3	2	2	1	1	1	1	1				
			08.RETARDATION	1	1	1	1	1	1	1	1	1				
			09.AGITATION	2	2	1	1	0	0	0	0	0				
			10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1				
			11.ANXIETY SOMATIC	3	3	2	1	0	1	1	1	1				
			12.SOMATIC GASTROINTESTINAL	1	2	2	1	1	1	1	1	1				
			13.SOMATIC GENERAL	1	2	2	1	1	1	1	1	1				
14.CENTRAL SYMPTOMS	0	1	1	1	0	1	0	0	0							
15.HYPochondriasis	2	2	1	1	1	1	1	0	0							
16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0							
17.INSIGHT	2	2	2	1	1	0	0	0	0							
18.DIURNAL VARIATION	2	2	1	1	0	0	0	0	0							
19.DEPERSONALIZATION	2	2	1	1	0	0	0	0	0							
20.PARANOID	1	1	1	0	0	0	0	0	0							

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120

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PHARMACIA CNS 3&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0
 HAMILTON DEPRESSION RATING SCALE

Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8/A 237	Female	21. OBSESSIONAL/COMPULSIVE 22. Total score	32	1	1	1	1	0	1	1
238	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3	3	2	2	2	1	1	1
239	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	28	3	2	2	2	1	1	1

1213

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121

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8/A	240	Imipramine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2
				02. GUILT	2	2	2	1	1	1	1	0
				03. SUICIDE	2	2	1	1	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	0	1	1	0	1	0	0	0
				06. INSOMNIA LATE	1	1	2	2	1	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	2
				08. RETARDATION	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	1	0	0	1
				10. ANXIETY PSYCHIC	1	2	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	1	1	2	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	27	29	26	21	19	16	16	14
553		Placebo	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2
				02. GUILT	3	3	2	2	1	1	1	1
				03. SUICIDE	1	1	1	1	1	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	1	2	2
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	1	1	2	1	1	1	1	1
				07. WORK AND ACTIVITIES	4	3	2	2	2	2	2	1
				08. RETARDATION	2	2	3	2	2	2	2	2
				09. AGITATION	1	1	1	0	1	0	1	0
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	0	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	1	1	1	1	1	1	1	1
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1
				22. Total score	29	29	27	23	21	18	20	17
554		Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	2	2	1	1
				02. GUILT	3	2	2	1	1	0	0	0
				03. SUICIDE	1	1	1	1	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	1	1	1	2

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122

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8/A	554	Reboxetine	Male	05. INSOMNIA MIDDLE	1	1	0	0	0	0	0	0
				06. INSOMNIA LATE	2	2	1	1	1	1	1	0
				07. WORK AND ACTIVITIES	4	4	3	2	2	1	1	1
				08. RETARDATION	1	1	1	1	1	1	1	1
				09. AGITATION	1	1	1	1	0	0	0	0
				10. ANXIETY PSYCHIC	1	1	1	1	0	0	0	0
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1
				22. Total score	27	26	22	17	14	12	10	9
	555	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2
				02. GUILT	2	2	1	1	1	1	0	0
				03. SUICIDE	1	1	1	1	1	0	0	0
				04. INSOMNIA EARLY	2	2	2	1	1	1	2	1
				05. INSOMNIA MIDDLE	1	1	0	0	0	0	0	0
				06. INSOMNIA LATE	1	1	2	2	1	1	0	1
				07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	1
				08. RETARDATION	1	1	1	1	1	1	1	1
				09. AGITATION	2	1	0	0	1	1	1	0
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	2	2	1	1	1	1
				14. GENITAL SYMPTOMS	2	1	1	2	1	1	1	1
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	1	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	2	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	1	1	1	1	1	1	1	1
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	29	29	23	19	18	17	16	13
	556	Imipramine	Male	01. DEPRESSED MOOD	3	3	2	2	1	1	1	1
				02. GUILT	2	2	2	1	1	1	1	0
				03. SUICIDE	1	1	1	1	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	2	1	2	1
				05. INSOMNIA MIDDLE	1	0	0	0	1	1	0	0
				06. INSOMNIA LATE	2	2	1	0	0	0	0	1
				07. WORK AND ACTIVITIES	4	4	3	2	2	2	1	1
				08. RETARDATION	1	1	1	1	1	1	1	1

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123

PHARMACIA CNS R&D
REBOXYTINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8/A	556	Imipramine	Male	09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	31	1	1	0	0	0	0	0
9	241	Placebo	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3	4	1	1	4	4	1	1
242	Reboxetine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL	3	3	1	1	3	3	1	2	1

1216

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124

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PHARMACIA CNS RD
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient Treatment	Sex	HAMILTON DEPRESSION RATING SCALE																			
			Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42				
9	242	Reboxetine	Female	13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
				16. LOSS OF WEIGHT	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				18. DIURNAL VARIATION	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				22. Total score	31	28	17	25	29													
				243	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
							02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
							08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
13. SOMATIC GENERAL	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2				
14. GENITAL SYMPTOMS	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0				
15. HYPOCHONDRIASIS	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0				
16. LOSS OF WEIGHT	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1				
17. INSIGHT	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0				
18. DIURNAL VARIATION	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0				
19. DEPERSONALIZATION	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0				
20. PARANOID	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0				
22. Total score	22	22	22				22	22	22	22	22	22	22	22	22	22	22	22				
244	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
			02. GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
			08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1					

1217

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125

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42					
9	244	Imipramine	Female	17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				22. Total score	23	23	14	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
				01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
07. WORK AND ACTIVITIES	4	4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
14. GENITAL STRPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
15. HIPCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
16. LOSS OF WEIGHT	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
20. PARANOID	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
22. Total score	23	24	20	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13	13				
246	246	Placebo	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4			
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				09. AGITATION	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
				10. ANXIETY PSYCHIC	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
14. GENITAL STRPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
15. HIPCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					

1218

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126

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	7	14	21	28	35	42
9	246	Placebo	Female	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	33	31	32	32	30	30	30	30
	247	Placebo	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	2	2
				02. GUILT	2	2	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	2	2	2	2	2	2
				06. INSOMNIA LATE	1	1	1	1	1	1	2	2
				07. WORK AND ACTIVITIES	4	4	3	2	3	3	3	3
				08. RETARDATION	0	0	0	0	0	0	0	0
				09. ACITATION	0	0	0	0	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	1	2	2	2	2
				11. ANXIETY SOMATIC	3	3	3	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	1	1	0	1	1	1	1	1
				16. LOSS OF HEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	25	25	23	20	24	23	24	23
	248	Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3
				02. GUILT	2	2	2	2	2	2	2	2
				03. SUICIDE	1	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	1	1	1	1	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	2	2	2	2	2	2
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4
				08. RETARDATION	1	1	1	1	1	1	1	1
				09. ACITATION	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	2	3	3	3	3	3
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF HEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	22	23	26	26	26	26	26	26

1219

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127

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	249	Reboxetine	Female	HAMILTON DEPRESSION RATING SCALE		3	2	2	2	2	2	2
				01. DEPRESSED MOOD		3	2	2	2	2	2	2
				02. GUILT		2	2	2	2	2	2	2
				04. INSOMNIA EARLY		1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE		2	2	2	2	2	2	2
				06. INSOMNIA LATE		2	0	0	0	0	0	0
				07. WORK AND ACTIVITIES		3	3	3	3	3	3	3
				08. RETARDATION		2	2	2	2	2	2	2
				09. AGITATION		0	1	1	1	1	1	1
				10. ANXIETY PSYCHIC		2	2	2	2	2	2	2
				11. ANXIETY SOMATIC		1	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL		1	1	1	1	1	1	1
				13. SOMATIC GENERAL		1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS		2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS		0	0	0	0	0	0	0
				16. LOSS OF WEIGHT		3	3	3	3	3	3	3
				17. INSIGHT		0	0	0	0	0	0	0
				18. DIURNAL VARIATION		0	0	0	0	0	0	0
				19. DEPERSONALIZATION		0	0	0	0	0	0	0
				20. PARANOID		0	0	0	0	0	0	0
				21. OBSSSSIONAL/COMPULSIVE		0	0	0	0	0	0	0
				22. Total score		27	25	25	25	25	25	25
250		Imipramine	Female	HAMILTON DEPRESSION RATING SCALE		3	3	3	3	3	3	3
				01. DEPRESSED MOOD		3	3	3	3	3	3	3
				02. GUILT		1	1	1	1	1	1	1
				03. SUICIDE		2	2	2	2	2	2	2
				04. INSOMNIA EARLY		2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE		2	1	1	1	1	1	1
				06. INSOMNIA LATE		1	2	2	2	2	2	2
				07. WORK AND ACTIVITIES		3	3	3	3	3	3	3
				08. RETARDATION		2	2	2	2	2	2	2
				09. AGITATION		0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC		1	1	1	1	1	1	1
				11. ANXIETY SOMATIC		0	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL		1	1	1	1	1	1	1
				13. SOMATIC GENERAL		2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS		0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS		0	0	0	0	0	0	0
				16. LOSS OF WEIGHT		0	0	0	0	0	0	0
				17. INSIGHT		0	0	0	0	0	0	0
				18. DIURNAL VARIATION		1	1	1	1	1	1	1
				19. DEPERSONALIZATION		0	0	0	0	0	0	0
				20. PARANOID		0	0	0	0	0	0	0
				21. OBSSSSIONAL/COMPULSIVE		0	0	0	0	0	0	0
				22. Total score		23	25	23	18	20	20	21
251		Imipramine	Female	HAMILTON DEPRESSION RATING SCALE		4	4	4	4	4	4	4
				01. DEPRESSED MOOD		4	4	4	4	4	4	4
				02. GUILT		2	2	2	2	2	2	2
				03. SUICIDE		3	3	3	3	3	3	3
				04. INSOMNIA EARLY		1	1	1	1	1	1	1

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1220

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128

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9	251	Imipramine	Female	05. INSOMNIA MIDDLE	0	0	1	1	0	0	0	0				
				06. INSOMNIA LATE	0	0	1	1	1	1	1					
				07. WORK AND ACTIVITIES	4	4	3	3	1	1	1					
				08. RETARDATION	2	2	1	0	0	0	0					
				09. AGITATION	1	1	0	0	0	0	0					
				10. ANXIETY PSYCHIC	2	2	1	2	0	0	0					
				11. ANXIETY SOMATIC	1	1	1	2	1	1	1					
				12. SOMATIC GASTROINTESTINAL	1	1	0	1	0	0	0					
				13. SOMATIC GENERAL	0	0	1	2	0	0	0					
				14. GENITAL SYMPTOMS	2	2	2	2	0	0	0					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	2	2	2	2	0	0	0					
				17. INSIGHT	2	2	2	1	0	0	0					
				18. DIURNAL VARIATION	0	0	1	1	0	0	0					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	27	27	19	25	5	4	4					
				252	Reboxetine	Female	01. DEPRESSED MOOD	3	3	4	4	4	4	4	4	4
							02. GUILT	1	1	1	1	1	1	1		
							03. SUICIDE	1	1	1	1	1	1	1		
							04. INSOMNIA EARLY	2	2	2	2	2	2	2		
05. INSOMNIA MIDDLE	2	2	2				2	2	2	2						
06. INSOMNIA LATE	1	1	2				2	2	2	2						
07. WORK AND ACTIVITIES	3	3	3				3	3	3	3						
08. RETARDATION	0	0	1				1	0	0	0						
09. AGITATION	1	1	2				3	4	4	4						
10. ANXIETY PSYCHIC	2	2	2				2	3	4	4						
11. ANXIETY SOMATIC	2	2	2				2	3	4	4						
12. SOMATIC GASTROINTESTINAL	0	0	1				1	1	1	1						
13. SOMATIC GENERAL	2	2	2				2	2	2	2						
14. GENITAL SYMPTOMS	2	2	2				2	2	2	2						
15. HYPOCHONDRIASIS	0	0	0				0	0	0	0						
16. LOSS OF WEIGHT	0	0	0				0	1	1	1						
17. INSIGHT	0	0	0				0	0	0	0						
18. DIURNAL VARIATION	0	0	0				0	0	0	0						
19. DEPERSONALIZATION	0	0	0				0	0	0	0						
20. PARANOID	0	0	0				0	0	0	0						
21. OBSESSIONAL/COMPULSIVE	0	0	0				0	0	0	0						
22. Total score	22	24	27				30	33	33	33						
253	Reboxetine	Female	01. DEPRESSED MOOD	4	4	3	3	0	0	0	0	0				
			02. GUILT	1	1	0	0	0	0	0						
			03. SUICIDE	2	2	3	3	2	2	2						
			04. INSOMNIA EARLY	2	2	2	2	2	2	2						
			05. INSOMNIA MIDDLE	2	2	2	2	2	2	2						
			06. INSOMNIA LATE	2	2	2	2	2	2	2						
			07. WORK AND ACTIVITIES	3	3	3	3	3	3	3						
08. RETARDATION	2	2	2	2	2	2	2									

1221

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129

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9	253	Reboxetine	Female	09. AGITATION	0	0	2									
				10. ANXIETY PSYCHIC	1	1	4									
				11. ANXIETY SOMATIC	2	2	2									
				12. SOMATIC GASTROINTESTINAL	0	0	1									
				13. SOMATIC GENERAL	2	2	2									
				14. GENITAL SYMPTOMS	2	2	2									
				15. HYPOCHONDRIASIS	1	1	1									
				16. LOSS OF WEIGHT	0	0	0									
				17. INSIGHT	0	0	0									
				18. DIURNAL VARIATION	0	0	1									
				19. DEPERSONALIZATION	0	0	0									
				20. PARANOID	0	0	0									
				21. OBSESSIONAL/COMPULSIVE	0	0	0									
				22. Total score	26	26	30									
				254	254	Imipramine	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4
								02. GUILT	1	1	1	1	1	1	1	
								03. SUICIDE	2	2	2	2	2	2	2	
								04. INSOMNIA EARLY	0	0	2	2	2	2	2	
								05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	
								06. INSOMNIA LATE	2	2	2	2	2	2	2	
								07. WORK AND ACTIVITIES	3	3	4	4	4	4	4	
								08. RETARDATION	1	1	1	1	1	1	1	
09. AGITATION	2	2	3					3	3	3	3					
10. ANXIETY PSYCHIC	3	3	4					4	4	4	4					
11. ANXIETY SOMATIC	3	3	4					4	4	4	4					
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	1					
13. SOMATIC GENERAL	2	2	2					2	2	2	2					
14. GENITAL SYMPTOMS	1	1	1					1	1	1	1					
15. HYPOCHONDRIASIS	1	1	1					1	1	1	1					
16. LOSS OF WEIGHT	2	2	0					0	0	0	0					
17. INSIGHT	0	0	0					0	0	0	0					
18. DIURNAL VARIATION	2	2	2					2	2	2	2					
19. DEPERSONALIZATION	0	0	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	32	30	36													
255	255	Reboxetine	Female	01. DEPRESSED MOOD	1	1	1	1	1	1	1	2				
				02. GUILT	1	1	1	1	1	1	1					
				03. SUICIDE	2	2	2	2	2	2	3					
				04. INSOMNIA EARLY	1	1	1	2	2	2	2					
				05. INSOMNIA MIDDLE	1	1	1	2	2	2	2					
				06. INSOMNIA LATE	0	1	1	2	2	2	2					
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3					
				08. RETARDATION	2	2	2	1	1	1	1					
				09. AGITATION	1	1	1	2	2	2	4					
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	4					
				11. ANXIETY SOMATIC	2	2	2	2	2	2	3					
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0					

1222

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130

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42						
9	255	Reboxetine	Female	13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				20. PARANOIA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				21. OBSESSIVE/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				22. Total score	22	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23		
				256	Imipramine	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
							02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							03. SUICIDE	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
							04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
							08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
							09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
13. SOMATIC GENERAL	1	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
14. GENITAL SYMPTOMS	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
15. HYPOCHONDRIASIS	3	3	3				3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
16. LOSS OF WEIGHT	2	1	1				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
17. INSIGHT	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
18. DIURNAL VARIATION	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
19. DEPERSONALIZATION	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
20. PARANOIA	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
21. OBSESSIVE/COMPULSIVE	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
22. Total score	33	32	32				32	32	32	32	32	32	32	32	32	32	32	32	32	32	32	32			
257	Placebo	Male	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4					
			08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					

1222

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131

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PHARMACIA CNS RD
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
9	Placebo	Male	17. INSIGHT	0	0	0	0	0	0	0			
			18. DIURNAL VARIATION	1	1	1	1	1	1	1	1		
			19. DEPERSONALIZATION	0	0	0	0	0	0	0	0		
			20. PARANOID	0	0	0	0	0	0	0	0		
			21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0		
			22. Total score	25	25	23							
			258	Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3
						02. GUILT	2	2	2	2	2	2	2
						03. SUICIDE	1	1	1	1	1	1	1
						04. INSOMNIA EARLY	1	1	1	1	1	1	1
						05. INSOMNIA MIDDLE	1	1	1	1	1	1	1
						06. INSOMNIA LATE	1	1	2	2	2	2	2
07. WORK AND ACTIVITIES	4	4				4	4	4	4	4			
08. RETARDATION	0	0				0	0	0	0	0			
09. AGITATION	1	1				1	1	1	1	1			
10. ANXIETY PSYCHIC	2	2				2	2	2	2	2			
11. ANXIETY SOMATIC	1	1				1	1	1	1	1			
12. SOMATIC GASTROINTESTINAL	1	1				1	1	1	1	1			
13. SOMATIC GENERAL	2	2	2	2	2	2	2						
14. CERILIAL SHREPTOMS	1	1	1	1	1	1	1						
15. HIPOCHONDRIASIS	1	1	2	2	2	2	2						
16. LOSS OF WEIGHT	1	1	0	0	0	0	0						
17. INSIGHT	1	1	1	1	1	1	1						
18. DIURNAL VARIATION	1	1	1	1	1	1	1						
19. DEPERSONALIZATION	0	0	0	0	0	0	0						
20. PARANOID	0	0	0	0	0	0	0						
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0						
22. Total score	26	26	30										
11	Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3			
			02. GUILT	2	2	2	2	2	2	2			
			03. SUICIDE	3	3	2	2	2	2	2			
			04. INSOMNIA EARLY	2	2	1	1	1	1	1			
			05. INSOMNIA MIDDLE	1	1	0	0	0	0	0			
			06. INSOMNIA LATE	2	2	2	2	2	2	2			
			07. WORK AND ACTIVITIES	2	2	2	2	2	2	2			
			08. RETARDATION	1	1	1	1	1	1	1			
			09. AGITATION	2	2	2	2	2	2	2			
			10. ANXIETY PSYCHIC	3	3	3	3	3	3	3			
			11. ANXIETY SOMATIC	1	1	1	1	1	1	1			
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1			
13. SOMATIC GENERAL	1	1	1	1	1	1	1						
14. CERILIAL SHREPTOMS	1	1	1	1	1	1	1						
15. HIPOCHONDRIASIS	0	0	0	0	0	0	0						
16. LOSS OF WEIGHT	2	2	0	0	0	0	0						
17. INSIGHT	0	0	0	0	0	0	0						
18. DIURNAL VARIATION	2	2	2	2	2	2	2						
19. DEPERSONALIZATION	0	0	0	0	0	0	0						
20. PARANOID	0	0	0	0	0	0	0						

1224

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132

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PIARNACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
11	319	Placebo	Male	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	29	27	24	25	28	26	24	22						
320		Imipramine	Male	01.DEPRESSED MOOD	3	3	4	2	4	2	2	3	2	2	3	2	2	2
				02.GUILT	1	1	2	1	2	2	1	1	1	1	1	1	1	1
				03.SUICIDE	2	2	2	1	2	1	1	1	1	1	1	1	1	1
				04.INSOMNIA EARLY	2	2	2	1	2	1	1	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	1	2	1	1	1	1	1	1	1	1	1
				06.INSOMNIA LATE	2	2	2	1	2	1	1	1	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08.RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09.AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10.ANXIETY PSYCHIC	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				11.ANXIETY SOMATIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				12.SOMATIC GASTROINTESTINAL	1	0	1	0	2	1	2	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16.LOSS OF HEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	29	30	32	17	27	17	20	15						
321		Placebo	Male	01.DEPRESSED MOOD	3	3	3	2	2	1	1	1	1	1	1	1	1	1
				02.GUILT	2	2	1	2	1	1	1	1	1	1	1	1	1	1
				03.SUICIDE	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				04.INSOMNIA EARLY	0	1	1	0	0	0	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	0	0	1	1	1	1	1	1	1	1	1	1
				06.INSOMNIA LATE	1	1	1	0	1	1	1	1	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08.RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09.AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10.ANXIETY PSYCHIC	3	3	4	3	2	2	2	2	2	2	2	2	2	2
				11.ANXIETY SOMATIC	1	1	1	2	1	1	1	1	1	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16.LOSS OF HEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	1	2	2	2	2	2	2	2	2	2	2
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	22	23	23	16	14	7	4	3						

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133

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42	
11	322	Reboxetine	Female		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	2	3	2	1	1	1	1	1	1	1	1	1	1	1	1	2
				05. INSOMNIA MIDDLE	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	0
				06. INSOMNIA LATE	0	0	0	2	1	1	1	1	1	1	1	1	1	1	1	1
				07. WAKE AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	25	28	24	19	20	20	20	20	20	23	23	21				
323		Reboxetine	Male		2	2	2	1	1	1	1	1	1	1	0	0	0	0	1	1
				01. DEPRESSED MOOD	2	2	2	1	1	1	1	1	1	1	0	0	0	0	0	1
				02. SUICIDE	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	2	2	1	1	1	1	1	1	0	0	0	0	0	0
				06. INSOMNIA LATE	2	2	2	1	1	1	1	1	1	1	0	0	0	0	0	0
				07. WAKE AND ACTIVITIES	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	1	1	1	1	1	1	1	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	2	2	2	2	1	1
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	25	25	17	10	8	5	5	5	5	5	5	5	5	5	6	6
324		Imipramine	Male		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1

1226

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134

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42					
11	324	Imipramine	Male	05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
				07. MORR AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				08. RETARDATION	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
				09. AGITATION	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				17. INSIGHT	2	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				19. DEPERSONALIZATION	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				22. Total score	24	24	27	22	20	24	24	24	24	24	24	24	24	24	24	24	24		
				325	Reboxetine	Male	01. DEPRESSED MOOD	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
							02. GUILT	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0
							03. SUICIDE	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
05. INSOMNIA MIDDLE	1	1	1				0	0	0	0	0	0	0	0	0	0	0	0	0				
06. INSOMNIA LATE	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2				
07. MORR AND ACTIVITIES	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2				
08. RETARDATION	1	1	1				0	0	0	0	0	0	0	0	0	0	0	0	0				
09. AGITATION	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0				
10. ANXIETY PSYCHIC	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2				
11. ANXIETY SOMATIC	1	1	2				1	1	1	1	1	1	1	1	1	1	1	1	1				
12. SOMATIC GASTROINTESTINAL	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2				
13. SOMATIC GENERAL	2	2	2				2	2	2	2	2	2	2	2	2	2	2	2	2				
14. GENITAL SYMPTOMS	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0				
15. HYPOCHONDRIASIS	1	1	1				0	0	0	0	0	0	0	0	0	0	0	0	0				
16. LOSS OF WEIGHT	2	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0				
17. INSIGHT	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0				
18. DIURNAL VARIATION	2	2	1				1	1	1	1	1	1	1	1	1	1	1	1	1				
19. DEPERSONALIZATION	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0				
20. PARANOID	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	0	0				0	0	0	0	0	0	0	0	0	0	0	0	0				
22. Total score	23	22	14				7	5	3	3	3	3	3	3	3	3	3	3	3				
326	Placebo	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
			02. GUILT	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0					
			03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			07. MORR AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
			08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					

1227

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135

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	7	14	21	28	35	42
11	326	Placebo	Male	09. ACITATION	1	0	0	2	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	4	3	3	1	1	1
				11. ANXIETY SOMATIC	0	0	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	2	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	1	1	1
				14. GENITAL SYMPTOMS	0	0	0	0	0	2	2	2
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	1	2
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	23	22	23	24	21	24	25	23
327		Imipramine	Male	01. DEPRESSED MOOD	2	2	1	0	0	0	0	0
				02. GUILT	2	2	0	0	0	0	0	0
				03. SUICIDE	2	2	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	0	0	0	0	0	0
				06. INSOMNIA LATE	2	2	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	1	1	2	2	1	1	1	1
				08. RETARDATION	1	1	1	1	0	0	0	0
				09. AGITATION	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	23	23	9	9	9	9	9	9
328		Imipramine	Female	01. DEPRESSED MOOD	4	2	2	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2
				03. SUICIDE	2	2	1	1	1	1	1	1
				04. INSOMNIA EARLY	2	2	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	1	1	1	1	1	1
				06. INSOMNIA LATE	1	0	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	1	1	1	1	1	1
				09. AGITATION	2	2	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	4	3	2	2	2	2	2	2
				11. ANXIETY SOMATIC	3	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	2	1	1	1	1	1	1	1

1228

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136

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42		
11	328	Imipranine	Female	13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
329		Placebo	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RESTABATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
330		Reboxetine	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RESTABATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0

1229

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137

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42				
11	330	Reboxetine	Male	17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	25	24	26	17	15	14	9	8										
				01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
05. INSOMNIA MIDDLE	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
06. INSOMNIA LATE	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
08. RETARDATION	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2				
12. SOMATIC GASTROINTESTINAL	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
13. SOMATIC GENERAL	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
22. Total score	22	19	13	10	10	4	10	12	13													
332	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
			02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
			03. SUICIDE	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
			04. INSOMNIA EARLY	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
			05. INSOMNIA MIDDLE	2	2	1	1	1	2	0	0	0	0	0	0	0	0	0	0	0		
			06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
			07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
			08. RETARDATION	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0		
			09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
			10. ANXIETY PSYCHIC	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
18. DIURNAL VARIATION	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0					
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					

1230

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139

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PHARMACIA CNS RD
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	332	Reboxetine	Male	21. OBSESSIONAL/COMPULSIVE 22. Total score	26	0	0	0	0	0	0	0
	333	Placebo	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF HEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	26	2	2	2	1	1	1	1
	334	Reboxetine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF HEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	26	3	2	2	2	2	2	2

1231

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139

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 42.0

HAMILTON DEPRESSION RATING SCALE

Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	335	Placebo	Male	2	2	2	2	2	1
		01..DEPRESSED MOOD	2	2	2	2	2	2	2
		02..GUILT	2	2	2	2	2	2	2
		03..SUICIDE	1	1	0	0	0	0	0
		04..INSOMNIA EARLY	0	0	0	0	0	0	0
		05..INSOMNIA MIDDLE	1	1	1	2	2	2	1
		06..INSOMNIA LATE	0	0	1	2	2	2	2
		07..WORRY AND ACTIVITIES	2	2	2	1	2	2	2
		08..RETARDATION	1	1	1	1	1	1	1
		09..AGITATION	1	1	0	0	0	0	0
		10..ANXIETY PSYCHIC	3	3	2	2	2	2	2
		11..ANXIETY SOMATIC	3	3	2	2	2	2	2
		12..SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0
		13..SOMATIC GENERAL	2	2	2	2	2	2	2
		14..GENITAL SYMPTOMS	1	1	1	0	0	0	0
		15..HYPOCHONDRIASIS	1	0	0	0	0	0	0
		16..LOSS OF WEIGHT	2	0	0	0	0	0	0
		17..INSIGHT	0	0	0	0	0	0	0
		18..DIURNAL VARIATION	0	0	0	0	0	0	0
		19..DEPERSONALIZATION	0	0	0	0	0	0	0
		20..PARANOID	0	0	0	0	0	0	0
		21..OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0
		22..Total score	23	20	15	16	15	17	14
336	Imipramine	Female	3	3	3	3	3	3	3
		01..DEPRESSED MOOD	3	3	3	3	3	3	3
		02..GUILT	1	1	1	1	1	1	1
		03..SUICIDE	2	2	2	2	2	2	2
		04..INSOMNIA EARLY	1	1	1	1	1	1	1
		05..INSOMNIA MIDDLE	1	1	1	1	1	1	1
		06..INSOMNIA LATE	2	2	2	2	2	2	2
		07..WORRY AND ACTIVITIES	3	3	3	3	3	3	3
		08..RETARDATION	2	2	2	2	2	2	2
		09..AGITATION	0	0	0	0	0	0	0
		10..ANXIETY PSYCHIC	2	2	2	2	2	2	2
		11..ANXIETY SOMATIC	3	3	3	3	3	3	3
		12..SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1
		13..SOMATIC GENERAL	2	2	2	2	2	2	2
		14..GENITAL SYMPTOMS	0	0	0	0	0	0	0
		15..HYPOCHONDRIASIS	1	1	1	1	1	1	1
		16..LOSS OF WEIGHT	0	0	0	0	0	0	0
		17..INSIGHT	0	0	0	0	0	0	0
		18..DIURNAL VARIATION	0	0	0	0	0	0	0
		19..DEPERSONALIZATION	0	0	0	0	0	0	0
		20..PARANOID	0	0	0	0	0	0	0
		21..OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0
		22..Total score	25	25	26	26	26	26	26
337	Reboxetine	Female	2	2	2	2	2	2	2
		01..DEPRESSED MOOD	2	2	2	2	2	2	2
		02..GUILT	1	1	1	1	1	1	1
		03..SUICIDE	1	1	1	1	1	1	1
		04..INSOMNIA EARLY	2	2	2	2	2	2	2

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
11	337	Reboxetine Female	05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	2 2 1 0 2 1 0 2 2 2 2 2 2 2 1 2 2 2 2 2 2 2 23	1 2 2 1 0 1 1 2 2 2 2 2 2 2 0 0 0 0 0 0 0 23	2 2 1 0 2 1 1 2 2 2 2 2 2 1 1 2 2 2 2 2 2 24	2 2 1 0 2 1 1 2 2 2 2 2 2 1 1 2 2 2 2 2 2 25	2 2 1 0 2 1 1 2 2 2 2 2 2 1 1 2 2 2 2 2 2 25	0 2 1 0 2 1 1 2 2 2 2 2 2 1 1 2 2 2 2 2 2 25	2 2 1 0 2 1 1 2 2 2 2 2 2 1 1 2 2 2 2 2 2 25	
12	367	Reboxetine Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3 3 0 2 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 24	3 2 0 2 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 24	1 1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 24	0 24	1 1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 24	1 1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 24	0 24	0 24

1233

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141

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
12	367	Reboxetine	Female	09. ACTIVATION	3	2	2	2	0	1	0	1	
				10. ANXIETY PSYCHIC	2	0	1	2	0	0	0	0	0
				11. ANXIETY SOMATIC	1	2	1	2	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	0	0	0	0	0
				14. GENITAL SYMPTOMS	1	1	0	0	0	1	0	0	0
				15. HYPOCHONDRIASIS	2	0	0	0	2	0	0	0	0
				16. LOSS OF WEIGHT	2	2	0	2	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	1	1	1	0	0	0	0	0
				19. DEPERSONALIZATION	1	1	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0
21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	1	0	0	0				
22. Total score	32	27	13	17	6	3	1	3	1	10			
368	Placebo	Female	01. DEPRESSED MOOD	3	3	1	3	1	1	1	2	1	
			02. GUILT	1	1	1	0	0	0	0	0	0	
			03. SUICIDE	0	0	0	0	0	0	0	0	0	
			04. INSOMNIA EARLY	2	1	1	0	0	0	0	0	1	
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	
			06. INSOMNIA LATE	2	2	2	1	1	1	1	1	1	
			07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	
			08. RETARDATION	2	2	2	3	2	1	1	1	1	
			09. AGITATION	1	0	0	0	0	0	0	0	0	
			10. ANXIETY PSYCHIC	3	3	3	1	1	2	1	0	0	
			11. ANXIETY SOMATIC	1	1	1	2	0	0	1	0	0	
			12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	
13. SOMATIC GENERAL	1	1	1	1	1	1	1	0	0				
14. GENITAL SYMPTOMS	2	2	2	2	2	2	0	0	0				
15. HYPOCHONDRIASIS	1	2	2	2	0	0	0	0	0				
16. LOSS OF WEIGHT	1	2	0	0	0	0	0	0	0				
17. INSIGHT	0	0	0	0	0	0	0	0	0				
18. DIURNAL VARIATION	1	1	0	0	0	0	0	0	0				
19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0				
20. PARANOID	0	0	0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0	0	0	0				
22. Total score	25	24	19	18	11	9	11	10	11				
369	Imipramine	Female	01. DEPRESSED MOOD	3	3	0	2	0	4	2	4	1	
			02. GUILT	2	1	0	1	0	1	2	0	0	
			03. SUICIDE	4	4	0	0	0	0	3	0	0	
			04. INSOMNIA EARLY	1	1	1	0	1	1	1	1	1	
			05. INSOMNIA MIDDLE	2	2	0	1	1	1	1	1	1	
			06. INSOMNIA LATE	1	1	0	0	1	1	1	1	1	
			07. WORK AND ACTIVITIES	3	3	1	1	1	1	4	1	1	
			08. RETARDATION	1	1	0	0	0	0	0	0	0	
			09. AGITATION	1	2	1	2	1	2	3	2	3	
			10. ANXIETY PSYCHIC	2	1	1	1	2	1	2	3	1	
			11. ANXIETY SOMATIC	2	1	1	1	2	1	2	3	1	
			12. SOMATIC GASTROINTESTINAL	1	0	0	0	0	0	0	0	0	

1234

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142

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42	
12	369	Imipramine	Female	13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	30	27	7	1	1	0	0	0	0	0	0	0	0	0	33
370		Placebo	Male	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	3	3	2	1	0	2	3	2	1	0	2	3	3	3	3
371		Imipramine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2

1235

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143

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
12	371	Imipramine	Female	17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	2	1	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	0	1	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	32	25	10											
372		Reboxetine	Male	01. DEPRESSED MOOD	3	4	3	2	1	1	1	1	0	0	0	0	0	3
				02. GUILT	2	3	2	2	0	0	0	0	0	0	0	0	0	2
				03. SUICIDE	2	3	2	2	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	2	0	0	0	0	0	0	0	0	0	1
				05. INSOMNIA MIDDLE	2	2	2	2	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	1	2	0	0	1	0	0	0	0	0	0	0	0	1
				07. WORK AND ACTIVITIES	3	3	3	2	1	1	0	0	0	0	0	0	0	1
				08. RETARDATION	2	2	1	1	1	1	0	0	0	0	0	0	0	1
				09. AGITATION	2	2	1	1	1	1	0	1	0	1	0	0	0	1
				10. ANXIETY PSYCHIC	3	2	3	2	1	1	1	1	1	3	1	0	0	3
				11. ANXIETY SOMATIC	2	3	2	1	2	1	1	1	1	0	0	0	0	1
				12. SOMATIC GASTROINTESTINAL	1	0	1	1	2	0	0	0	0	0	0	0	0	1
				13. SOMATIC GENERAL	1	2	1	1	1	1	1	1	1	0	0	0	0	1
				14. GENITAL SYMPTOMS	2	2	1	1	1	1	1	1	1	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	1	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	2	0	2	2	2	2	2	2	2	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	0	1	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	1	1	1	1	1	1	1	1	1	1	1	1	1
				21. OBSESSIONAL/COMPULSIVE	0	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	32	34	24	15	8	7	8	7	7	2	2	2	2	19
373		Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	2	2	2	2	2	2	1	1	1	1	0
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				03. SUICIDE	3	3	3	2	3	3	3	3	3	2	2	2	2	0
				04. INSOMNIA EARLY	2	2	2	2	1	2	2	2	2	2	2	2	2	1
				05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	0	0	0	0	0	0	1
				06. INSOMNIA LATE	2	1	0	2	0	2	0	2	2	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	3	3	1	3	2	2	2	2	2	2	2	0
				08. RETARDATION	0	1	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	2	2	2	2	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	2	0	3	0	0	1	0	0	0	0	0
				11. ANXIETY SOMATIC	2	2	0	0	0	0	0	0	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	0	1	0	1	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	0	1	0	1	0	1	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	1	1	0	2	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	2	2	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	2	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	1	2	1	2	1	2	1	2	2	2	2	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0

1236

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144

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
12	373	Reboxetine	Male	21. OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0	0	2	1	1	1	0			
				22. Total score	32	30	11	21	10	17	9	3							
	374	Placebo	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	1	0	1						
				02. GUILT	2	2	2	1	0	0	1	1							
				03. SUICIDE	3	2	0	0	0	0	0	0	1						
				04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0						
				05. INSOMNIA MIDDLE	1	0	0	0	0	0	0	0	0						
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0	2						
				07. MORE AND ACTIVITIES	2	2	2	1	2	1	2	1	1						
				08. RETARDATION	2	2	1	0	2	1	0	2	1						
				09. AGITATION	2	2	1	0	1	0	1	0	1						
				10. ANXIETY PSYCHIC	3	4	3	2	2	2	1	1	1						
				11. ANXIETY SOMATIC	2	2	2	0	1	1	1	1							
				12. SOMATIC GASTROINTESTINAL	0	1	1	0	0	0	0	0							
				13. SOMATIC GENERAL	1	1	1	1	1	0	0	0							
				14. GENITAL SYMPTOMS	2	2	1	1	1	1	1	1							
				15. HYPOCHONDRIASIS	1	0	0	0	0	0	0	0	0						
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0						
				17. INSIGHT	0	0	0	0	0	0	0	0	0						
				18. DIURNAL VARIATION	1	1	1	0	0	0	0	0	0						
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0						
				20. PARANOID	0	0	0	0	0	0	0	0	0						
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1						
				22. Total score	26	25	18	8	12	11	11								
	375	Imipramine	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3							
				02. GUILT	3	3	3	3	3	3	3	3							
				03. SUICIDE	2	2	2	2	2	2	2	2							
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1							
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1							
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1							
				07. MORE AND ACTIVITIES	2	2	2	2	2	2	2	2							
				08. RETARDATION	2	2	2	2	2	2	2	2							
				09. AGITATION	1	1	1	1	1	1	1	1							
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1							
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1							
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1							
				13. SOMATIC GENERAL	0	0	0	0	0	0	0	0							
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0							
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0							
				16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2							
				17. INSIGHT	0	0	0	0	0	0	0	0							
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0							
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0							
				20. PARANOID	1	1	1	1	1	1	1	1							
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1							
				22. Total score	24	24	26	24	26	24	26	24							

1237

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PHARMACIA CNS RED
 REMOXTINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	13	Placebo	Male	01. DEPRESSED MOOD	2	2	2	1	2	2	2	3
				02. GUILT	3	3	2	2	2	2	2	
				03. SUICIDE	3	3	0	0	1	0	1	2
				04. INSOMNIA EARLY	0	0	1	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	1	1	1	0	1	1
				06. INSOMNIA LATE	2	2	1	0	1	1	0	0
				07. WORK AND ACTIVITIES	3	3	1	2	2	1	2	2
				08. RETARDATION	1	1	1	1	0	1	1	2
				09. AGITATION	2	2	1	1	0	1	1	0
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	0	0	0	1
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	1	1	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score				24	24	16	14	17
14	14	Placebo	Male	01. DEPRESSED MOOD	3	3	1	3	3	0	2	1
				02. GUILT	2	2	0	3	1	0	1	1
				03. SUICIDE	2	2	0	0	1	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	2	1	0
				05. INSOMNIA MIDDLE	0	0	0	1	0	0	1	0
				06. INSOMNIA LATE	0	0	0	0	0	0	0	1
				07. WORK AND ACTIVITIES	2	2	1	2	2	1	1	1
				08. RETARDATION	2	2	0	2	1	0	1	1
				09. AGITATION	1	1	1	2	1	0	1	1
				10. ANXIETY PSYCHIC	2	2	1	2	1	1	1	2
				11. ANXIETY SOMATIC	2	2	0	2	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	0
				14. GENITAL SYMPTOMS	1	1	0	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	0	1	1	0	0	1
				16. LOSS OF WEIGHT	1	1	0	1	1	1	1	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	2	2	2	1	2	2
				19. DEPERSONALIZATION	0	0	1	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score				25	25	12	23	21
15	15	Imipramine	Female	01. DEPRESSED MOOD	3	3	2	1	1	3	3	3
				02. GUILT	2	2	1	1	1	1	1	1
				03. SUICIDE	4	4	1	0	0	1	1	2
				04. INSOMNIA EARLY	2	2	1	1	2	2	2	1

12338

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146

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
13	15	Imipramine	Female	05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1				
				06. INSOMNIA LATE	1	1	1	0	0	1	0	1				
				07. WORK AND ACTIVITIES	2	2	2	2	1	1	3	2	2			
				08. RETARDATION	2	2	1	1	1	1	1	1	1			
				09. AGITATION	1	1	1	0	1	2	1	1	1			
				10. ANXIETY PSYCHIC	1	1	1	0	1	1	1	1	1			
				11. ANXIETY SOMATIC	2	2	1	1	2	1	1	1	1			
				12. SOMATIC GASTROINTESTINAL	0	0	1	1	0	1	1	1	1			
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1			
				14. GENITAL SYMPTOMS	2	2	1	1	1	1	1	1	1			
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0			
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0			
				17. INSIGHT	0	0	0	0	0	0	0	0	0			
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2			
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0			
				20. PARANOID	1	1	1	1	1	1	1	1	1			
				21. OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	0	0			
				22. Total score	28	28	19	13	16	24	21	21	21			
				16	16	Imipramine	Male	01. DEPRESSED MOOD	2	2	3	2	2	1	1	1
								02. GUILT	2	2	2	2	0	1	1	1
								03. SUICIDE	0	0	1	1	0	0	0	0
								04. INSOMNIA EARLY	1	2	2	1	1	1	1	0
05. INSOMNIA MIDDLE	2	2	1					1	0	1	2	2				
06. INSOMNIA LATE	2	2	2					1	1	1	1	2				
07. WORK AND ACTIVITIES	2	1	2					2	1	1	1	1				
08. RETARDATION	1	1	2					2	1	0	1	1				
09. AGITATION	2	2	2					2	2	1	2	2				
10. ANXIETY PSYCHIC	2	2	1					2	2	1	1	1				
11. ANXIETY SOMATIC	1	1	2					2	1	1	1	2				
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	0	0	0				
13. SOMATIC GENERAL	1	1	1					1	1	1	1	1				
14. GENITAL SYMPTOMS	0	0	1					1	1	0	0	1				
15. HYPOCHONDRIASIS	1	1	2					2	2	1	1	2				
16. LOSS OF WEIGHT	0	0	0					0	0	0	0	0				
17. INSIGHT	0	0	0					0	0	0	0	0				
18. DIURNAL VARIATION	1	1	2					2	0	2	2	2				
19. DEPERSONALIZATION	1	1	1					1	1	0	0	1				
20. PARANOID	0	0	0					0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	1	1	0					0	0	0	0	0				
22. Total score	22	22	28					23	9	16	16	24				
17	17	Reboxetine	Male	01. DEPRESSED MOOD	2	2	2	2	1	1	1	1				
				02. GUILT	2	2	2	1	0	0	0					
				03. SUICIDE	2	2	1	0	0	0	0					
				04. INSOMNIA EARLY	0	0	0	0	0	0	0					
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1					
				06. INSOMNIA LATE	0	0	0	0	0	0	0					
				07. WORK AND ACTIVITIES	2	2	1	1	1	1	2					
				08. RETARDATION	1	1	1	1	1	1	1					

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147

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42							
13	17	Reboxetine	Male	09. AGITATION	2	2	2	1	1	2	2	2	0	0	0	0	2								
				10. ANXIETY PSYCHIC	2	2	1	2	2	2	2	2	2	2	1	1	1	1							
				11. ANXIETY SOMATIC	2	2	1	2	2	2	2	2	2	2	2	2	2	2	1	1					
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				13. SOMATIC GENERAL	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				15. HYPOCHONDRIASIS	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				19. DEPERSONALIZATION	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				20. PARANOID	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				22. Total score	24	24	15	13	11	10	10	10	10	10	10	10	10	10	10	10	11				
				18	18	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2			
								02. GUILT	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0		
								03. SUICIDE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
								04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
								05. INSOMNIA MIDDLE	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	
								06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
								07. WORK AND ACTIVITIES	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
								08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
09. AGITATION	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2					
10. ANXIETY PSYCHIC	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2					
11. ANXIETY SOMATIC	2	2	0					0	0	0	0	0	0	0	0	0	0	0	0	0					
12. SOMATIC GASTROINTESTINAL	2	2	2					2	2	2	2	2	2	2	2	2	2	2	2	2					
409	409	Reboxetine	Male	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2							
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1						
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1						
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2						
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2						
				07. WORK AND ACTIVITIES	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1						
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1						
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
				11. ANXIETY SOMATIC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					

1240

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148

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
13	409	Reboxetine	Male	13. SOMATIC GENERAL	2	2	1	1	1	0	0				
				14. GENITAL SYMPTOMS	1	1	0	1	0	0					
				15. HYPOCHONDRIASIS	1	1	2	1	2	1					
				16. LOSS OF WEIGHT	0	0	0	0	0	1					
				17. INSIGHT	0	0	0	0	0	0					
				18. DIURNAL VARIATION	2	2	2	2	2	2					
				19. DEPERSONALIZATION	0	0	1	0	0	0					
				20. PARANOID	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0					
				22. Total score	24	24	24	19	19	14					
				410		Placebo	Male	01. DEPRESSED MOOD	2	2	3	3	2	2	2
								02. GUILT	1	1	2	1	0	1	
								03. SUICIDE	2	1	1	1	0	0	
								04. INSOMNIA EARLY	1	2	1	2	0	2	
								05. INSOMNIA MIDDLE	0	1	1	0	0	1	
								06. INSOMNIA LATE	0	0	1	0	1	1	
								07. WORK AND ACTIVITIES	2	2	2	2	2	2	
								08. RETARDATION	1	2	1	1	1	1	
								09. AGITATION	2	1	2	1	2	2	
								10. ANXIETY PSYCHIC	3	1	2	2	2	1	
								11. ANXIETY SOMATIC	3	2	2	2	2	3	
								12. SOMATIC GASTROINTESTINAL	0	1	1	1	1	1	
13. SOMATIC GENERAL	1	1	1					1	1	1					
14. GENITAL SYMPTOMS	2	2	2					2	2	1					
15. HYPOCHONDRIASIS	0	0	1					0	0	0					
16. LOSS OF WEIGHT	0	0	1					0	0	0					
17. INSIGHT	0	0	0					0	0	0					
18. DIURNAL VARIATION	0	0	2					2	0	0					
19. DEPERSONALIZATION	1	1	1					1	0	0					
20. PARANOID	0	1	1					0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	1	1					0	1	0					
22. Total score	23	24	25					30	23	15	24	16			
411		Imipramine	Female	01. DEPRESSED MOOD	3	3	1	0	3	2	1				
				02. GUILT	0	0	0	0	0	1					
				03. SUICIDE	2	2	0	0	0	0					
				04. INSOMNIA EARLY	1	1	0	0	0	0					
				05. INSOMNIA MIDDLE	1	1	0	0	0	0					
				06. INSOMNIA LATE	1	1	0	0	0	0					
				07. WORK AND ACTIVITIES	2	2	1	1	2	2					
				08. RETARDATION	1	1	1	1	2	2					
				09. AGITATION	1	1	1	1	0	0					
				10. ANXIETY PSYCHIC	1	1	1	1	2	2					
				11. ANXIETY SOMATIC	2	2	2	2	2	2					
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	1	0					
				13. SOMATIC GENERAL	1	1	1	1	2	2					
				14. GENITAL SYMPTOMS	0	0	0	0	1	1					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	4	4	1	0	2	0					

1241

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149

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RD
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.6

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day					
13	411	Female	Imipramine	17. INSIGHT	0	0	0	0	0	0	0	0				
				18. DIURNAL VARIATION	1	1	2	0	1	0	0	0				
				19. DEPERSONALIZATION	0	0	1	0	0	2	1	0				
				20. PARANOID	0	0	0	1	1	1	0	1				
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0	0	0				
				22. Total score	23	23	15	9	18	26	20	9				
				423	423	Male	Placebo	01. DEPRESSED MOOD	2	2	2	2	2	2	0	0
								02. GUILT	2	2	1	1	2	0	0	0
								03. SUICIDE	1	1	1	0	1	1	1	1
								04. INSOMNIA EARLY	1	1	1	1	1	1	1	1
								05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1
								06. INSOMNIA LATE	2	2	0	1	1	1	1	1
07. WORK AND ACTIVITIES	2	2	2					2	2	2	2	2				
08. RETARDATION	1	1	1					1	1	2	2	0				
09. AGITATION	2	2	0					1	1	2	0	0				
10. ANXIETY PSYCHIC	2	2	1					1	1	1	1	1				
11. ANXIETY SOMATIC	1	1	0					0	0	0	0	0				
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	0	0	0				
13. SOMATIC GENERAL	2	2	1	0	1	0	1	1								
14. GENITAL SYMPTOMS	0	0	0	0	1	1	1	0								
15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0								
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0								
17. INSIGHT	0	0	0	0	0	0	0	0								
18. DIURNAL VARIATION	2	2	0	0	1	1	1	1								
19. DEPERSONALIZATION	0	0	0	2	1	1	1	0								
20. PARANOID	0	0	0	0	1	0	1	0								
21. OBSESSIONAL/COMPULSIVE	1	1	1	0	1	1	1	1								
22. Total score	22	22	13	15	20	20	17	7								
14	19	Female	Reboxetine	01. DEPRESSED MOOD	4	4	4	4	3	4	4					
				02. GUILT	1	1	1	0	1	1	1					
				03. SUICIDE	1	2	1	1	2	2	2					
				04. INSOMNIA EARLY	2	2	2	2	2	2	2					
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2					
				06. INSOMNIA LATE	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	4	4	4	2	3	4	4					
				08. RETARDATION	3	3	3	1	2	3	3					
				09. AGITATION	3	3	3	1	1	1	1					
				10. ANXIETY PSYCHIC	3	3	3	1	3	3	3					
				11. ANXIETY SOMATIC	3	2	2	0	1	0	2					
				12. SOMATIC GASTROINTESTINAL	0	1	1	0	1	0	1					
13. SOMATIC GENERAL	2	1	1	0	1	0	0									
14. GENITAL SYMPTOMS	0	0	0	0	0	0	0									
15. HYPOCHONDRIASIS	3	1	3	0	1	1	1									
16. LOSS OF WEIGHT	0	1	2	0	0	0	0									
17. INSIGHT	0	0	0	0	0	0	0									
18. DIURNAL VARIATION	0	1	0	0	2	2	2									
19. DEPERSONALIZATION	3	2	2	0	1	1	1									
20. PARANOID	0	1	0	0	1	1	1									

1243

9550082

150

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14	19	Reboxetine	Female	21. OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0	0	0
				22. Total score	37	36	14	29	31			
20		Imipramine	Female	01. DEPRESSED MOOD	3	3	2	1	1	1	0	0
				02. GUILT	2	2	1	1	1	1	0	1
				03. SUICIDE	1	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	1	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	2	1	1	1	0	0
				06. INSOMNIA LATE	2	2	2	1	1	1	0	0
				07. WORK AND ACTIVITIES	3	3	3	1	1	0	0	1
				08. RETARDATION	1	1	1	0	0	0	0	0
				09. AGITATION	2	2	2	1	1	1	0	0
				10. ANXIETY PSYCHIC	3	3	3	1	1	1	0	0
				11. ANXIETY SOMATIC	1	1	2	1	0	0	0	1
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	1	0	0	0	0	0
				16. LOSS OF HEIGHT	3	3	0	0	0	0	0	0
				17. INSIGHT	1	1	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	2	2	1	1	1	1
				19. DEPERSONALIZATION	0	0	1	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	29	29	27	18	9	7	2	3
21		Imipramine	Female	01. DEPRESSED MOOD	4	3	2	3	3	3	3	3
				02. GUILT	2	0	0	1	1	1	1	1
				03. SUICIDE	3	1	0	0	3	3	1	1
				04. INSOMNIA EARLY	1	2	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	2	1	1	1	1	1	1
				06. INSOMNIA LATE	0	2	2	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	2	2	3	2	3	3
				08. RETARDATION	1	1	1	0	1	1	1	1
				09. AGITATION	2	1	2	2	3	2	2	2
				10. ANXIETY PSYCHIC	3	3	3	1	3	1	0	2
				11. ANXIETY SOMATIC	1	1	2	1	1	1	0	2
				12. SOMATIC GASTROINTESTINAL	1	1	2	0	2	0	0	2
				13. SOMATIC GENERAL	0	2	0	0	1	1	0	2
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	1	3	3	2	2	2	2	2
				16. LOSS OF HEIGHT	1	1	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	1	1	1	2	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	25	29	25	16	28	21	24	

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

151

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42					
15	25	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2				
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				06. INSOMNIA LATE	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				09. AGITATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				20. PARANOID	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score				27	27	26	27	24	20	22	21								
26		Placebo	Male	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2				
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				06. INSOMNIA LATE	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				20. PARANOID	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				22. Total score				28	28	21	18	15	19	14	10								
27		Imipramine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2				
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2			
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		

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152

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day			
15	27	Imipramine Female	05. INSOMNIA MIDDLE	1	1	1	1	1	0	1			
			06. INSOMNIA LATE	2	0	0	0	0	0				
			07. WORK AND ACTIVITIES	2	2	2	1	1	0				
			08. RETARDATION	1	1	0	1	0	0				
			09. AGITATION	1	1	1	0	1	1				
			10. ANXIETY PSYCHIC	3	2	2	2	1	1				
			11. ANXIETY SOMATIC	2	1	2	1	0	0				
			12. SOMATIC GASTROINTESTINAL	1	0	1	0	0	0				
			13. SOMATIC GENERAL	2	2	1	0	1	1				
			14. GENITAL SYMPTOMS	2	2	1	2	1	1				
			15. HYPOCHONDRIASIS	0	0	0	0	0	0				
			16. LOSS OF WEIGHT	0	0	0	0	0	0				
			17. INSIGHT	0	0	0	0	0	0				
			18. DIURNAL VARIATION	1	1	1	1	0	0				
			19. DEPERSONALIZATION	0	0	0	0	0	0				
			20. PARANOID	0	0	0	0	0	0				
			21. OBSESSIONAL/COMPULSIVE	1	1	0	1	0	0				
			22. Total score	27	27	18	20	11	8	6			
			28	Reboxetine Female	01. DEPRESSED MOOD	3	3	2	1	1	1	1	0
					02. GUILT	1	1	2	1	1	1	1	1
					03. SUICIDE	1	1	1	1	1	1	1	0
					04. INSOMNIA EARLY	1	1	1	1	1	1	1	0
05. INSOMNIA MIDDLE	2	2			2	1	0	0	1	0			
06. INSOMNIA LATE	1	1			1	0	0	0	0	0			
07. WORK AND ACTIVITIES	2	2			2	2	1	2	1	1			
08. RETARDATION	0	0			0	0	0	0	0	0			
09. AGITATION	1	1			1	0	0	0	0	0			
10. ANXIETY PSYCHIC	2	2			2	2	2	1	2	1			
11. ANXIETY SOMATIC	1	1			0	1	0	0	1	1			
12. SOMATIC GASTROINTESTINAL	1	1			0	0	0	0	0	0			
13. SOMATIC GENERAL	2	2			1	0	0	1	1	1			
14. GENITAL SYMPTOMS	2	2			2	1	1	1	1	0			
15. HYPOCHONDRIASIS	0	0			0	0	0	0	0	0			
16. LOSS OF WEIGHT	0	0			0	0	0	0	0	0			
17. INSIGHT	0	0			0	0	0	0	0	0			
18. DIURNAL VARIATION	1	1			1	1	1	1	1	0			
19. DEPERSONALIZATION	1	1			0	0	0	0	0	0			
20. PARANOID	0	0			0	0	0	0	0	0			
21. OBSESSIONAL/COMPULSIVE	1	1			0	0	0	0	0	0			
22. Total score	24	24			19	12	10	10	12	5			
29	Placebo Male	01. DEPRESSED MOOD	3	3	3	2	2	3					
		02. GUILT	2	2	2	2	2	2					
		03. SUICIDE	1	1	1	1	1	0					
		04. INSOMNIA EARLY	0	0	0	0	0	1					
		05. INSOMNIA MIDDLE	1	1	1	1	1	1					
		06. INSOMNIA LATE	2	2	1	1	1	1					
		07. WORK AND ACTIVITIES	3	3	3	3	3	3					
		08. RETARDATION	1	1	1	1	1	1					

1245

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153

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0
 HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
15	29	Placebo	Male	09. ACITATION	0	0	0	1	1	1	1	1					
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3					
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1					
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2					
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2					
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0					
				17. INSIGHT	1	1	1	1	1	1	1	1					
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1					
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1					
				22. Total score	28	28	28	27	27	27	26	26					
30		Imipramine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	1	1	2	1	1	1	1
				02. GUILT	2	2	2	2	2	2	1	1	2	1	1	1	1
				03. SUICIDE	1	1	1	1	1	1	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	0	0	0	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	1	1	1	1	1	1	0	1	1	1	1
				06. INSOMNIA LATE	0	0	0	1	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	1	2	1	2	1	1	1
				08. RETARDATION	1	1	1	1	1	1	0	0	0	0	0	0	0
				09. ACITATION	1	1	1	1	1	1	0	0	1	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	2	2	2	2	2	2	2	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	0	0	1	1	1	1	0	0	1	0	0	0	0
				13. SOMATIC GENERAL	1	1	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	2	2	2	2	2	2	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	24	24	24	24	21	21	10	16	9	11	11	11	11
403		Imipramine	Female	01. DEPRESSED MOOD	3	3	1	2	1	1	1	1	1	1	1	1	1
				02. GUILT	2	2	1	1	1	1	1	1	0	0	0	0	0
				03. SUICIDE	1	1	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	0	1	1	1	1
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	0	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	2	2	2	2	2	2	1	1	1	1	1
				08. RETARDATION	1	1	1	1	1	1	1	1	0	0	0	0	0
				09. ACITATION	1	1	1	1	1	1	1	1	0	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	1	1	1	1	1
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1

1246

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154

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	403	Imipramine	Female	13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIVE/COMPULSIVE 22. Total score	27	2	1	1	1	1	1	1
404	404	Reboxetine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIVE/COMPULSIVE 22. Total score	23	3	2	2	2	2	2	3
405	405	Placebo	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION 09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GENERAL 14. GENITAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT	23	3	2	3	1	1	1	1

1247

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155

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42	
15	405	Placebo	Female	17. INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	25	25	21	20	10	10	10	7	5						
406		Imipramine	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. CENTRAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	23	23	16	15	10	9	6	11							
407		Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
				02. GUILT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				08. RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. CENTRAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

1248

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156

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42
15	407	Reboxetine	Female	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	28	23	22	17	17	17	13	14					
	408	Placebo	Female	01. DEPRESSED MOOD	3	3	3	3	2	1	1	1	1	1	1	1	1	1
				02. GUILT	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				03. SUICIDE	1	1	1	1	2	1	1	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	2	2	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	1	1	1	1	1	2	2	1	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	1	1	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	4	4	4	4	2	2	2	2	2	2	2	2	2	2
				08. RETARDATION	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	3	2	2	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	29	29	28	28	17	16	16	13	13					
	418	Placebo	Female	01. DEPRESSED MOOD	3	3	3	3	2	2	2	2	2	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				03. SUICIDE	1	1	1	1	1	0	1	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	1	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	0	0	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	3	2	3	3	2	1	0	0	0	0	0
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	2	2	2	2	1	1	1	1	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	3	3	2	2	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	28	28	25	23	20	20	20	11	7					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	419	Placebo	Female	01. DEPRESSED MOOD	3	2	2	2	2	1	2	2
				02. GUILT	2	1	2	2	1	1	1	1
				03. SUICIDE	1	1	0	1	1	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	0	0
				05. INSOMNIA MIDDLE	2	2	1	2	1	1	0	0
				06. INSOMNIA LATE	1	1	0	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2
				08. RETARDATION	0	0	0	0	0	0	0	0
				09. AGITATION	1	1	0	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	2	2	2	2	2
				11. ANXIETY SOMATIC	1	1	1	1	2	1	2	1
				12. SOMATIC GASTROINTESTINAL	1	1	0	1	1	0	0	0
				13. SOMATIC GENERAL	2	2	0	2	2	2	2	2
				14. GENITAL SYMPTOMS	1	1	1	2	1	1	1	1
				15. HYPOCHONDRIASIS	2	2	1	1	2	1	1	1
				16. LOSS OF WEIGHT	2	2	0	0	0	0	0	0
				17. INSIGHT	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	1	1	1	0	0	1	0	0
				19. DEPERSONALIZATION	0	0	1	0	0	0	0	1
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	25	14	21	20	15	15	15	12

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.83	1.83	2.17	1.17	1.00	0.67	0.50
				2. WEIGHT	2.00	2.00	2.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	1.00	1.83	1.00	0.67	0.50	0.33
				4. DIURNAL VARIATION	2.00	2.00	2.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.50	2.50	2.75	1.00	0.75	1.00	0.50
				6. SLEEP DISTURBANCE	2.00	2.00	1.00	1.67	2.00	0.67	0.33
				7. Total score	11.33	11.33	11.75	4.83	4.42	3.83	1.50
2		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.17	1.67	1.83	0.83	1.17	0.83	1.00
				2. WEIGHT	0.00	0.00	2.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.83	1.33	0.83	0.83	0.83	0.67	0.50
				4. DIURNAL VARIATION	0.00	1.00	0.00	1.00	1.00	1.00	0.00
				5. RETARDATION	3.00	2.25	2.50	1.75	1.50	2.00	1.25
				6. SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	2.00	2.00	1.00
				7. Total score	8.00	8.25	8.83	5.75	5.50	6.50	4.75
3		Imipramine	Male	1. ANXIETY/SOMATIZATION	1.00	1.17	1.17	1.33	1.00	0.50	0.33
				2. WEIGHT	1.00	1.00	2.00	1.00	0.00	1.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.17	0.33	0.33	0.33
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.00	2.00	1.75	2.00	1.50	1.50	1.25
				6. SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	0.67	1.00
				7. Total score	5.67	5.83	6.58	5.50	3.83	3.33	2.17
4		Placebo	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	0.67	0.83	0.67	0.67	0.50
				2. WEIGHT	2.00	2.00	2.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.17	0.17	0.00	0.00
				4. DIURNAL VARIATION	0.00	0.00	0.00	1.00	1.00	0.00	0.00
				5. RETARDATION	2.25	2.25	1.50	0.75	0.50	0.25	0.25
				6. SLEEP DISTURBANCE	1.67	1.67	1.00	0.67	0.67	0.33	0.33
				7. Total score	8.08	8.08	5.83	3.42	3.00	1.25	1.08
5		Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.00	0.83	0.83		
				2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.83	1.00		
				4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00		
				5. RETARDATION	2.00	2.00	2.00	2.00	2.00		
				6. SLEEP DISTURBANCE	2.00	2.00	1.67	1.67	1.67		
				7. Total score	10.17	10.17	6.50	6.33	6.30		
6		Placebo	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.00	1.00	1.00	0.33	0.67
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.33	1.33	0.67	0.50	0.83	0.50	1.00
				4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	1.00
				5. RETARDATION	2.50	2.50	1.50	1.25	1.25	1.25	1.25
				6. SLEEP DISTURBANCE	1.33	1.33	1.67	2.00	2.00	1.00	1.33
				7. Total score	7.50	7.50	4.83	4.75	6.08	3.08	5.25

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
1	7	Female	Reboxetine	1. ANXIETY/SOMATIZATION	1.67	1.00	0.63	0.50	0.33	0.33	0.17	
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	1.00	0.83	0.83	0.33	0.00	0.00	0.00	
				4. DIURNAL VARIATION	1.00	1.00	0.00	1.00	0.00	0.00	0.00	
				5. RETARDATION	2.25	2.25	1.75	0.75	0.50	0.00	0.00	
				6. SLEEP DISTURBANCE	2.00	2.00	1.00	0.67	0.33	0.00	0.33	
				7. Total score	8.92	8.92	6.58	4.42	3.25	1.17	0.33	0.50
				8	8	Male	Placebo	1. ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.50
2. WEIGHT	1.00	1.00	0.00					0.00	0.00	0.00	0.00	
3. COGNITIVE DISTURBANCE	0.67	0.67	0.67					0.67	0.50	0.33	0.17	
4. DIURNAL VARIATION	2.00	2.00	1.00					0.00	0.00	0.00	0.00	
5. RETARDATION	1.50	1.50	1.25					1.00	0.75	0.50	0.50	
6. SLEEP DISTURBANCE	2.00	2.00	1.67					1.00	1.33	1.00	0.33	
7. Total score	8.50	8.50	5.42					3.17	3.25	2.83	2.17	1.08
9	9	Female	Reboxetine					1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.50
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	2.00	2.00	1.67	1.00	1.50	1.00	0.67	
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	
				5. RETARDATION	2.50	2.50	2.25	2.25	2.50	1.75	1.25	
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	1.00	1.33	
				7. Total score	10.83	10.83	8.83	6.75	9.50	5.42	5.08	3.25
				10	10	Male	Placebo	1. ANXIETY/SOMATIZATION	1.50	1.50	0.67	0.50
2. WEIGHT	0.00	0.00	0.00					0.00	0.00	0.00	0.00	
3. COGNITIVE DISTURBANCE	1.00	1.00	0.67					0.50	0.33	0.50	0.50	
4. DIURNAL VARIATION	1.00	1.00	1.00					1.00	1.00	1.00	1.00	
5. RETARDATION	1.50	1.50	1.75					1.00	1.25	1.00	1.00	
6. SLEEP DISTURBANCE	2.00	2.00	1.33					0.67	0.33	0.00	0.00	
7. Total score	7.00	7.00	5.42					2.67	2.75	2.50	2.33	2.17
11	11	Female	Imipramine					1. ANXIETY/SOMATIZATION	1.33	1.33		
				2. WEIGHT	1.00	1.00						
				3. COGNITIVE DISTURBANCE	0.50	0.50						
				4. DIURNAL VARIATION	1.00	1.00						
				5. RETARDATION	1.75	1.75						
				6. SLEEP DISTURBANCE	2.00	2.00						
				7. Total score	7.58	7.58						
				12	12	Female	Imipramine	1. ANXIETY/SOMATIZATION	0.83	0.83	1.17	0.67
2. WEIGHT	1.00	1.00	0.00					0.00	0.00	0.00	0.00	
3. COGNITIVE DISTURBANCE	1.17	1.17	0.67					0.33	0.17	0.50	0.00	
4. DIURNAL VARIATION	1.00	1.00	2.00					0.00	0.00	0.00	0.00	
5. RETARDATION	2.25	2.25	1.75					1.00	0.75	0.75	0.25	

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3

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

Centre Patient Treatment		Sex	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE									
			Hamilton depression rating scale									
			Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
1	12	Female	0.00	0.00	0.00	0.67	0.00	0.67	0.67	0.67	0.33	
			6.25	6.25	5.58	2.67	1.58	2.42	1.42	1.08		
	412	Male	1.33	1.33	0.83	0.83	0.83	1.00	0.17	0.33		
			1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00		
			1.00	1.00	0.83	0.67	0.67	0.17	0.00	0.00		
			1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00		
			2.25	2.25	1.75	1.50	1.50	1.50	0.50	0.50		
			1.33	1.33	1.00	2.00	1.00	0.67	1.00	0.00		
			7.92	7.92	5.42	5.00	4.00	3.33	1.67	0.83		
	413	Male	1.17	1.00	0.83	0.83	0.83	0.67	0.67	0.50		
			0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			1.17	1.17	1.00	0.83	0.83	1.00	0.50	0.50		
			1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00		
			1.25	2.00	2.00	0.75	1.50	1.50	1.00	1.00		
			1.00	2.00	0.67	0.33	0.33	0.00	0.00	0.00		
			5.58	7.17	5.50	2.75	2.75	3.17	2.00	2.00		
12	414	Female	1.17	1.00	1.17	1.17	1.17	0.67	0.50	0.33		
OR			0.00	2.00	0.00	2.00	0.00	0.00	0.00	0.00		
OR			1.17	0.33	0.17	0.50	0.33	0.17	0.00	0.00		
			2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			2.00	2.25	2.00	1.75	2.00	2.00	0.75	0.25		
			2.00	2.00	2.00	2.00	2.00	2.00	1.00	1.33		
			8.33	7.58	5.33	7.42	4.25	2.68	1.92	1.92		
	415	Male	1.00	1.00	1.00	0.67	0.50	0.33	0.50	0.33		
			0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00		
			0.83	0.83	0.83	0.33	0.33	0.17	0.00	0.00		
			0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00		
			1.50	1.50	1.00	1.25	0.75	0.75	0.25	0.25		
			1.67	1.67	2.00	1.00	1.33	1.00	1.00	1.33		
			5.00	5.00	5.83	4.25	3.75	2.68	1.92	1.92		
	416	Female	1.83	1.33	1.50	1.50	1.50	0.67	0.50	0.33		
			1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00		
			1.00	1.00	0.67	0.67	0.67	0.67	0.67	0.67		
			1.00	1.00	0.00	1.00	0.00	0.00	0.00	0.00		
			1.25	1.25	1.50	1.25	1.50	1.25	1.25	1.25		
			1.67	1.67	2.00	2.00	2.00	2.00	2.00	2.00		
			7.75	7.25	6.67	6.42	6.42	6.42	6.42	6.42		
	421	Male	1.00	1.00	0.83	0.83	0.50	0.17	0.67	0.50		
			0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00		
			0.67	0.67	0.67	0.33	0.17	0.00	0.00	0.00		

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
1	421	Imipramine	Male	4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
				5. RETARDATION	2.25	2.25	2.00	1.25	1.00	0.75	1.00	0.25
				6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.00	0.67	0.33	0.33	0.67
				7. Total score	6.58	6.58	5.83	3.42	2.33	1.25	2.00	1.42
				1. ANXIETY/SOMATIZATION	1.00	1.00	0.67	0.67	0.33	0.50	0.17	0.33
				2. WEIGHT	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.17	0.33	0.17	0.17	0.17
422	Imipramine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	1.50	1.50	1.25	1.25	1.00	0.50	0.25	0.00	
			6. SLEEP DISTURBANCE	1.67	1.67	1.33	0.00	0.67	0.33	0.33	0.67	
			7. Total score	7.00	7.00	5.92	4.08	2.17	1.67	0.92	1.17	
			1. ANXIETY/SOMATIZATION	1.00	1.00	0.67	0.67	0.33	0.50	0.17	0.33	
			2. WEIGHT	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.17	0.33	0.17	0.17	0.17	
2/1	49	Placebo	Female	4. DIURNAL VARIATION	1.33	1.17	1.33	0.67	0.33	0.17	0.17	0.00
				5. RETARDATION	0.00	0.00	0.33	0.00	0.00	0.00	0.00	0.00
				6. SLEEP DISTURBANCE	0.00	0.33	0.33	0.00	0.00	0.00	0.00	0.00
				7. Total score	2.50	2.50	2.00	0.50	0.00	0.00	0.00	0.00
				1. ANXIETY/SOMATIZATION	0.00	1.00	1.00	1.00	1.00	0.67	0.33	0.33
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.33	0.33	0.00	0.00	0.00	0.00	0.00
50	Reboxetine	Female	4. DIURNAL VARIATION	1.50	1.17	1.00	0.83	1.00	1.00	0.83	0.83	
			5. RETARDATION	0.50	0.50	0.00	0.17	0.00	0.00	0.00	0.00	
			6. SLEEP DISTURBANCE	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	
			7. Total score	2.00	1.75	0.75	0.25	0.00	0.00	0.00	0.00	
			1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	1.00	0.67	0.67	1.50	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	0.50	0.50	0.17	0.17	0.00	0.00	0.00	0.00	
51	Imipramine	Female	4. DIURNAL VARIATION	1.67	1.67	1.50	1.67	0.83	0.83	0.83	0.83	
			5. RETARDATION	0.00	0.00	2.00	0.00	0.00	0.00	2.00	0.00	
			6. SLEEP DISTURBANCE	1.17	1.17	0.50	0.17	0.17	0.00	0.00	0.00	
			7. Total score	0.00	0.00	0.00	1.00	1.00	2.00	2.00	2.00	
			1. ANXIETY/SOMATIZATION	2.75	2.25	2.00	1.50	0.75	0.50	0.50	0.50	
			2. WEIGHT	1.33	1.33	1.67	0.67	0.67	0.67	0.67	0.67	
			3. COGNITIVE DISTURBANCE	6.92	6.42	7.67	5.00	3.42	4.00	6.00	4.00	
2/2	43	Imipramine	Female	4. DIURNAL VARIATION	1.17	1.33	0.00	0.67	0.67	0.17	0.17	
				5. RETARDATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				6. SLEEP DISTURBANCE	1.00	1.17	0.50	0.17	0.17	0.00	0.00	
				7. Total score	1.00	1.00	1.00	2.00	2.00	0.00	0.00	
				1. ANXIETY/SOMATIZATION	1.75	1.50	0.00	1.25	0.25	0.25	0.25	
				2. WEIGHT	1.00	1.00	0.67	1.00	0.67	0.67	0.67	
				3. COGNITIVE DISTURBANCE	5.92	6.00	2.17	5.08	1.08	1.58	1.58	
44	Imipramine	Female	4. DIURNAL VARIATION	1.17	1.17	1.50	0.67	0.83	0.50	0.83	0.17	
			5. RETARDATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			6. SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			7. Total score	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	1.00		

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5

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day		
2/2	44	Imipramine	Female	Hamilton depression rating scale									
				2.WEIGHT	2.00	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.67	0.33	0.50	0.83	0.50	0.00
				4.DIURNAL VARIATION	1.00	2.00	1.00	1.00	2.00	1.00	1.00	1.00	1.00
				5.RETARDATION	1.00	1.25	1.00	0.25	0.75	0.25	0.25	0.25	0.00
				6.SLEEP DISTURBANCE	1.33	1.00	1.67	1.33	0.67	1.33	0.67	1.33	0.67
				7.Total score	7.33	6.25	7.83	3.92	4.58	2.92	4.25	2.33	
				45	Reboxetine	Female	Hamilton depression rating scale						
1.ANXIETY/SOMATIZATION	1.50	1.00	0.83				0.50	0.67	0.83	1.00	0.67		
2.WEIGHT	0.00	0.00	2.00				0.00	0.00	0.00	0.00	1.00		
3.COGNITIVE DISTURBANCE	1.17	1.58	0.33				0.67	0.33	0.67	0.67	0.17		
4.DIURNAL VARIATION	1.00	1.00	0.00				0.00	2.00	0.00	0.00	1.00		
5.RETARDATION	1.25	1.25	1.50				0.75	1.25	0.50	0.25	1.00		
6.SLEEP DISTURBANCE	1.00	0.67	0.67				0.67	0.33	0.00	0.67	0.67		
7.Total score	5.92	5.42	5.33				2.58	4.58	2.00	2.58	4.50		
46	Placebo	Female	Hamilton depression rating scale										
			1.ANXIETY/SOMATIZATION	1.17	1.17	0.50			0.83	0.17			
			2.WEIGHT	0.00	0.00	0.00			0.00	0.00			
			3.COGNITIVE DISTURBANCE	1.17	1.00	0.33			0.50	0.17			
			4.DIURNAL VARIATION	0.00	2.00	0.00			0.00	0.00			
			5.RETARDATION	1.50	1.25	1.00			0.75	0.25			
			6.SLEEP DISTURBANCE	1.67	1.67	1.00			0.33	0.33			
			7.Total score	5.50	7.08	1.83			2.42	0.92			
47	Placebo	Female	Hamilton depression rating scale										
			1.ANXIETY/SOMATIZATION	1.00	1.67	1.33	1.00	0.67	1.00	0.83			
			2.WEIGHT	0.00	1.00	0.00	0.00	0.00	0.00	0.00			
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.33	0.17	0.17	0.50	0.33			
			4.DIURNAL VARIATION	0.00	1.00	1.00	1.00	1.00	1.00	2.00			
			5.RETARDATION	2.75	2.50	2.50	1.75	1.50	2.50	2.50			
			6.SLEEP DISTURBANCE	0.67	1.67	1.67	0.33	0.33	0.67	0.67			
			7.Total score	5.08	8.50	7.83	4.25	3.67	5.33	5.33			
48	Reboxetine	Female	Hamilton depression rating scale										
			1.ANXIETY/SOMATIZATION	0.83	1.00	0.83	1.17	0.50	0.17	0.00			
			2.WEIGHT	0.00	0.00	2.00	0.00	2.00	0.00	0.00			
			3.COGNITIVE DISTURBANCE	0.67	0.83	0.33	0.33	0.00	0.33	0.17			
			4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00			
			5.RETARDATION	2.75	2.75	2.50	1.25	1.25	0.75	0.75			
			6.SLEEP DISTURBANCE	1.67	1.67	0.67	0.33	0.00	0.67	0.33			
			7.Total score	6.92	7.25	6.33	4.68	3.75	1.92	0.67			
2/3	36/A	Imipramine	Male	Hamilton depression rating scale									
				1.ANXIETY/SOMATIZATION	1.50	1.17	1.17	0.67	0.67	0.83	0.83		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.50	1.00	1.00	0.00	0.17	0.17	0.17		
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	2.25	2.50	2.50	1.00	1.00	0.50	0.50		
				6.SLEEP DISTURBANCE	2.00	1.33	1.33	0.67	0.67	0.67	0.67		
				7.Total score	6.25	6.00	6.00	2.33	2.50	2.17	2.17		

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PHARMACIA CNS R8D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
2/3	37	Female	Reboxetine	1. ANXIETY/SOMATIZATION	1.00	1.00	1.67	1.67	1.67	1.67	0.50	
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.33	0.33	0.50	0.33	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.25	2.25	1.75	2.25	1.50	1.50	1.50	0.75
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	1.67	1.67	1.67	1.33
				7. Total score	6.58	6.58	5.92	6.42	5.17	4.83	4.83	2.58
				38		Male	Placebo	1. ANXIETY/SOMATIZATION	1.83	1.83	1.50	1.67
2. WEIGHT	0.00	0.00	0.00					0.00	0.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	0.67	0.67	0.50					0.47	0.50	0.50	0.50	0.50
4. DIURNAL VARIATION	1.00	1.00	1.00					1.00	0.00	0.00	0.00	0.00
5. RETARDATION	2.25	2.50	2.00					2.00	1.50	1.25	0.75	0.75
6. SLEEP DISTURBANCE	2.00	2.00	1.33					1.33	1.33	1.33	1.00	1.33
7. Total score	7.75	8.00	6.33					6.33	4.67	4.23	2.92	3.25
39		Female	Imipramine					1. ANXIETY/SOMATIZATION	2.00	1.83	1.17	1.17
				2. WEIGHT	1.00	2.00	0.00	0.00	0.00	2.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.50	0.67	0.67	0.50	0.00	0.17	0.00	0.00
				4. DIURNAL VARIATION	0.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.50	2.25	2.00	1.50	1.25	0.50	0.25	0.00
				6. SLEEP DISTURBANCE	2.00	2.00	1.67	1.00	0.00	0.00	0.00	0.00
				7. Total score	8.00	9.75	7.17	5.17	2.42	3.17	0.92	0.50
				40		Female	Reboxetine	1. ANXIETY/SOMATIZATION	1.00	1.00	1.17	0.83
2. WEIGHT	2.00	2.00	0.00					0.00	0.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	0.50	0.50	0.67					0.50	0.50	0.00	0.17	0.17
4. DIURNAL VARIATION	0.00	0.00	0.00					0.00	0.00	0.00	0.00	0.00
5. RETARDATION	1.75	1.75	1.50					1.50	0.75	0.50	0.25	0.00
6. SLEEP DISTURBANCE	1.67	1.67	0.67					0.33	0.33	1.00	1.00	0.00
7. Total score	6.92	6.92	4.00					3.17	2.08	3.83	1.92	1.25
41		Male	Placebo					1. ANXIETY/SOMATIZATION	1.17	1.33	1.33	0.50
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	1.00	0.50	0.83	0.50	0.17	0.67	0.17
				4. DIURNAL VARIATION	1.00	1.00	2.00	1.00	2.00	2.00	2.00	2.00
				5. RETARDATION	2.50	2.50	2.50	2.75	2.75	2.25	2.25	2.50
				6. SLEEP DISTURBANCE	0.67	0.67	1.00	1.00	0.00	0.00	0.00	0.00
				7. Total score	6.33	6.50	7.33	5.83	5.75	6.42	5.42	5.50
				42		Female	Imipramine	1. ANXIETY/SOMATIZATION	1.83	1.67	1.17	1.33
2. WEIGHT	0.00	0.00	0.00					0.00	0.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	0.67	0.50	0.50					0.83	0.17	0.33	0.33	0.17
4. DIURNAL VARIATION	2.00	2.00	0.00					1.00	1.00	0.00	0.00	0.00
5. RETARDATION	2.25	2.25	2.00					1.75	0.75	1.50	1.25	1.50

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/3	42	Imipramine	Female	6.SLEEP DISTURBANCE 7.Total score	1.33 8.08	1.33 7.75	0.67 4.33	1.33 6.25	1.00 4.08	0.67 3.33	0.67 3.08
2/4	31	Placebo	Male	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 3.00 2.33 2.00 2.25 1.67 13.08	1.83 3.00 2.33 2.00 2.50 1.67 13.33	1.83 3.00 1.67 2.00 2.25 1.33 12.08	1.83 3.00 1.67 2.00 2.25 1.33 9.08	1.83 3.00 1.67 2.00 2.25 1.33 9.08	1.50 0.00 1.50 1.00 1.50 1.33 6.83	1.50 0.00 1.50 1.00 1.50 1.33 6.83
32		Reboxetine	Male	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.17 0.00 2.50 2.00 3.00 2.00 11.67	2.00 0.00 2.33 2.00 3.00 2.00 11.33	1.50 0.00 2.33 2.00 3.00 2.00 10.83	1.50 0.00 2.33 2.00 3.00 2.00 10.83	1.33 0.00 1.83 1.00 2.50 1.00 7.67	0.83 0.00 1.00 1.00 1.00 0.75 4.83	0.83 0.00 1.00 1.00 1.00 0.67 4.58
33		Imipramine	Male	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	0.50 0.00 2.00 2.00 1.50 2.00 8.00	0.50 0.00 2.00 2.00 1.50 2.00 8.00	0.50 0.00 2.00 2.00 1.50 2.00 8.00	0.50 0.00 2.00 2.00 1.50 2.00 8.00	0.33 0.00 1.33 1.00 1.25 1.33 5.25	0.33 0.00 0.83 0.50 0.75 1.00 3.08	0.33 0.00 0.50 0.00 0.50 0.00 1.33
34		Placebo	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	3.00 0.00 3.00 2.00 2.75 1.67 12.42	3.00 0.00 2.83 2.00 2.75 1.67 12.42	3.00 0.00 2.83 2.00 2.25 1.67 11.75	3.00 0.00 2.83 2.00 2.25 1.67 11.75	2.50 0.00 2.83 2.00 2.25 1.67 8.67	1.33 0.00 1.17 2.00 1.00 1.00 6.50	1.00 0.00 0.83 1.00 0.50 1.00 4.75
35		Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.83 0.00 2.50 1.00 2.25 2.00 10.58	2.83 0.00 2.50 1.00 2.25 2.00 11.58	2.17 0.00 2.00 2.00 2.25 2.00 10.92	2.17 0.00 2.00 2.00 2.25 2.00 9.83	1.33 0.00 1.50 1.00 1.50 1.67 7.00	0.83 0.00 0.67 0.00 0.75 0.67 5.00	0.83 0.00 0.50 0.00 0.75 0.00 2.92
36		Imipramine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE	2.33 0.00 2.83	2.33 0.00 2.83	2.17 0.00 3.00	2.17 0.00 2.50	1.50 0.00 1.50	1.00 0.00 1.00	0.50 0.00 0.50

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/4	36	Imipramine	Female	4. DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00	1.00
				5. RETARDATION	3.00	3.00	2.50	1.75	1.25	0.50	
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	0.00	0.00	
				7. Total score	12.17	12.17	12.33	11.17	7.75	4.25	2.50
2/5	73	Placebo	Male	1. ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.17	0.67	1.17	1.00
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.33	0.33	0.47	0.17	0.67	0.67	
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	1.00	1.00	
				5. RETARDATION	2.50	2.50	1.75	1.25	1.75	2.25	
				6. SLEEP DISTURBANCE	1.00	1.00	1.00	0.33	1.00	0.67	
				7. Total score	5.33	5.33	4.25	4.08	2.42	5.58	5.08
74		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.83	1.33	0.83	0.50	0.17	0.00	0.00
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.33	0.50	0.17	0.00	
				4. DIURNAL VARIATION	0.00	1.00	0.00	0.00	0.00	0.00	
				5. RETARDATION	2.00	2.25	1.50	0.75	0.50	0.25	
				6. SLEEP DISTURBANCE	1.00	1.33	1.00	1.00	1.00	0.67	
				7. Total score	5.50	6.58	3.67	2.75	1.83	1.50	
75		Imipramine	Male	1. ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.50	0.33	0.17	0.00
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	1.00	0.83	0.67	0.50	0.33	0.33	
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	
				5. RETARDATION	2.25	2.25	1.75	0.50	0.25	0.25	
				6. SLEEP DISTURBANCE	1.33	1.67	1.00	1.00	0.67	0.33	
				7. Total score	5.42	5.58	4.25	2.50	2.17	1.42	
76		Imipramine	Female	1. ANXIETY/SOMATIZATION	1.50	1.17	1.33	0.33	1.17	0.17	0.17
				2. WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	1.17	0.83	0.83	0.33	0.50	0.33	
				4. DIURNAL VARIATION	0.00	1.00	1.00	0.00	0.00	0.00	
				5. RETARDATION	2.00	2.50	2.00	1.00	2.25	1.25	
				6. SLEEP DISTURBANCE	1.33	1.00	1.00	1.00	0.33	0.33	
				7. Total score	7.00	6.50	6.17	2.67	3.92	2.08	
77		Placebo	Male	1. ANXIETY/SOMATIZATION	1.83	1.17	0.67	0.33	0.33	0.33	0.17
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.33	0.17	0.00	
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	
				5. RETARDATION	3.00	2.50	1.25	1.00	1.00	0.50	
				6. SLEEP DISTURBANCE	0.00	0.67	0.33	0.67	0.33	0.00	
				7. Total score	5.67	5.17	2.75	2.33	1.83	1.17	
78		Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.67	1.67	0.83	0.50	0.17	0.33	0.00

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REBOXETINE - PROTOCOL 2012A/015
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HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/5	78	Reboxetine	Female	2.WEIGHT	0.00	0.00	0.00	0.00	1.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.50	0.17	0.33	0.33
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.75	2.25	2.00	1.75	0.75	0.75	0.50
				6.SLEEP DISTURBANCE	0.67	0.67	1.00	1.00	0.67	0.33	0.33
				7.Total score	6.08	5.58	4.50	3.75	2.08	3.08	1.17
2/6	55	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.83	1.83	1.67	1.17	0.67	0.33	0.33
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.17	0.00	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.50	2.50	1.75	1.25	0.50	0.25
				6.SLEEP DISTURBANCE	1.67	1.67	0.67	0.33	0.00	0.00	0.00
				7.Total score	7.83	7.83	6.50	4.42	1.92	0.83	0.58
5/6	56	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.83	1.83	1.33	1.17
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.83	0.67	0.50	0.67
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	1.75	1.75	1.50	1.75	1.50	1.75	1.75
				6.SLEEP DISTURBANCE	1.00	1.00	0.33	0.00	0.00	0.00	0.67
				7.Total score	7.58	7.58	5.67	5.42	5.42	4.50	4.42
5/7	57	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.00	0.50	0.33	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.33	0.00	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.50	2.50	1.50	0.50	0.25	0.00
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.00	0.33	0.00	0.00
				7.Total score	7.33	7.33	6.17	3.83	1.00	0.92	0.17
5/8	58	Placebo	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	2.00	2.00	0.33	0.00	0.00
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.50	0.00	0.00	0.00
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.50	2.25	1.75	1.00	0.25	0.25
				6.SLEEP DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				7.Total score	6.83	6.83	6.58	4.25	1.33	0.25	0.25
5/9	59	Placebo	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.33	1.33	1.17	1.17
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.83	0.67	1.00	1.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	2.00	1.00	1.00
				5.RETARDATION	2.50	2.50	2.50	2.50	2.50	2.00	2.00
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.33	0.00	0.67	0.67
				7.Total score	8.17	8.17	6.33	6.08	6.50	5.83	5.83

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
276	60	Imipramine	Female	Hamilton depression rating scale	1.50	1.50	1.50	0.50	0.17	0.00	0.00	0.00
				1.ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				2.WEIGHT	0.83	0.83	0.67	0.33	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.25	2.25	2.00	1.25	0.75	0.75	0.50	0.50
				5.RETARDATION	1.33	1.33	1.33	0.67	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	6.92	6.92	6.50	3.75	0.92	0.75	0.50	0.50
				7.Total score	1.17	1.17	1.33	1.17	0.67	0.33	0.33	
3/1	61	Imipramine	Male	Hamilton depression rating scale	1.00	1.00	0.67	0.33	0.00	0.00	0.00	0.00
				1.ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.33	0.00	0.00	0.00	
				2.WEIGHT	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
				3.COGNITIVE DISTURBANCE	2.00	2.00	2.25	2.00	1.25	1.00	1.00	
				4.DIURNAL VARIATION	1.00	1.00	0.67	0.33	0.33	0.33	0.33	
				5.RETARDATION	6.83	6.83	5.92	5.17	3.25	1.67	1.67	
				6.SLEEP DISTURBANCE	1.50	1.50	0.83	0.50	0.33	0.17	0.33	
				7.Total score	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
62	62	Imipramine	Female	Hamilton depression rating scale	1.00	1.00	0.83	0.50	0.33	0.17	0.33	0.33
				1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	0.50	0.33	0.17	0.00	0.00
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.67	0.67	0.50	0.33	
				4.DIURNAL VARIATION	2.50	2.50	1.75	1.25	1.00	1.00	0.50	
				5.RETARDATION	1.33	1.33	1.67	1.33	0.67	0.33	0.33	
				6.SLEEP DISTURBANCE	6.33	6.33	3.58	2.75	1.83	1.67	1.17	
				7.Total score	1.50	1.00	1.17	1.00	1.00	0.50	0.50	
63	63	Placebo	Male	Hamilton depression rating scale	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				1.ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				2.WEIGHT	1.00	0.83	0.83	0.67	0.67	0.50	0.33	
				3.COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				4.DIURNAL VARIATION	2.75	2.50	2.25	1.75	1.75	1.00	1.00	
				5.RETARDATION	1.33	1.67	1.67	1.33	1.33	1.00	0.67	
				6.SLEEP DISTURBANCE	6.58	6.00	5.92	4.75	4.75	3.00	2.17	
				7.Total score	1.17	1.33	1.33	1.83	1.83	1.83	1.67	
64	64	Placebo	Female	Hamilton depression rating scale	0.83	0.83	0.67	0.50	0.50	0.50	0.33	0.33
				1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
				2.WEIGHT	2.25	2.25	2.00	2.75	2.75	2.50	2.50	
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.00	0.00	0.00	0.00	
				4.DIURNAL VARIATION	6.25	7.08	6.00	6.08	6.08	6.08	6.93	
				5.RETARDATION	1.00	1.67	1.00	0.00	0.00	0.67	0.33	
				6.SLEEP DISTURBANCE	1.50	1.67	1.17	1.17	0.83	0.67	0.33	
				7.Total score	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
65	65	Reboxetine	Male	Hamilton depression rating scale	1.00	1.00	1.00	0.83	0.67	0.33	0.33	
				1.ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				2.WEIGHT	1.00	1.00	1.00	0.50	0.33	0.33	0.17	
				3.COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				5.RETARDATION	2.75	2.50	1.50	1.50	0.75	1.00	1.00	

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
3/1	65	Reboxetine	Male	6.SLEEP DISTURBANCE	1.67	1.67	1.00	0.67	0.33	0.33	0.33		
				7.Total score	6.92	6.83	4.33	4.17	2.58	2.33	1.83	1.83	
66	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.50	1.33	1.00	0.83	0.33	0.33	0.50	0.50	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.17	0.17	0.17	0.17	0.17	0.00	0.00
			4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
			5.RETARDATION	2.50	2.50	2.25	1.50	1.50	1.25	1.25	1.25	1.25	1.25
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.33	0.33	0.00	0.33	0.00	0.33	0.33
			7.Total score	7.67	7.50	5.92	4.00	3.83	2.75	3.25	3.25	3.08	
139	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.67	0.67	1.00	1.67						
			4.DIURNAL VARIATION	2.00	2.00	2.00	3.00						
			5.RETARDATION	2.00	2.00	2.00	3.00						
			6.SLEEP DISTURBANCE	0.67	1.00	1.00	2.00						
			7.Total score	6.50	6.83	7.17	7.83						
140	Placebo	Male	1.ANXIETY/SOMATIZATION	1.83	1.83	1.67	1.33	1.00	0.83	0.50	0.67	0.67	
			2.WEIGHT	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.17	0.17	0.17	0.17	0.17	0.00	0.00
			4.DIURNAL VARIATION	2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5.RETARDATION	1.75	1.75	1.75	1.25	0.75	0.75	0.75	0.75	0.50	0.50
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.33	0.33	0.00	0.33	0.00	0.00	0.00
			7.Total score	9.08	9.08	7.75	3.08	2.25	1.92	1.75	1.75	1.17	
141	Placebo	Female	1.ANXIETY/SOMATIZATION	1.50	1.67	1.67	1.33	0.83	0.83	0.83	0.50	0.67	
			2.WEIGHT	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.33	0.33	0.33	0.33	0.17	0.17	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	1.50	1.50	1.50	1.00	0.50	1.00	1.00	1.00	0.50	0.50
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.00	0.00	0.33	0.33	0.00	0.33	0.67
			7.Total score	4.83	6.00	5.00	3.67	1.67	2.50	2.00	2.00	2.00	
142	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.33	1.33	1.33	1.33	1.33	1.33	
			2.WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.25	2.25	2.25	2.25	2.25	2.25	2.25	2.25	2.25	
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
			7.Total score	7.75	6.75	6.58	6.58	6.58	6.58	6.58	6.58	6.58	
143	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.17	1.17	1.17	0.67	0.67	0.83	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.83	1.00	0.67	0.33	0.33	0.33	0.33	0.33	0.17	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	143	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.25	2.25	1.00	0.75	0.75	0.75	
				6. SLEEP DISTURBANCE	0.33	0.33	0.33	0.33	0.33	0.33	
				7. Total score	5.58	5.75	4.17	3.08	3.08	3.08	
				1. ANXIETY/SOMATIZATION	0.83	0.83	1.17	1.00	1.17	0.83	0.83
				2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.83	0.33	0.33	0.33	0.33
4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
144	144	Reboxetine	Female	5. RETARDATION	2.00	2.00	2.00	1.00	0.75	0.50	0.50
				6. SLEEP DISTURBANCE	1.67	1.33	2.00	0.67	0.33	0.33	0.00
				7. Total score	7.17	6.83	6.00	3.00	2.58	2.00	1.67
				1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.50	1.50	1.50	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.33	0.33	0.33	
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	
451	451	Reboxetine	Female	5. RETARDATION	2.50	2.50	2.25	2.75	2.75	2.75	2.75
				6. SLEEP DISTURBANCE	1.33	1.67	1.67	1.67	1.67	1.67	
				7. Total score	5.67	6.00	5.58	6.25	6.25	6.25	
				1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.50	1.50	1.50	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.33	0.33	0.33	
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	
452	452	Placebo	Male	5. RETARDATION	2.75	2.75	1.75	0.50	0.00	0.00	0.00
				6. SLEEP DISTURBANCE	1.33	1.33	0.67	0.67	0.67	0.33	0.33
				7. Total score	7.58	7.42	3.42	1.50	0.67	0.33	2.17
				1. ANXIETY/SOMATIZATION	1.33	1.17	0.83	0.33	0.00	0.00	1.17
				2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.17	0.17	0.17	0.00	0.00	0.00	0.17
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
453	453	Imipramine	Female	5. RETARDATION	2.25	2.50	1.75	1.00	1.00	1.00	1.00
				6. SLEEP DISTURBANCE	1.00	1.00	1.00	0.67	0.33	0.33	0.33
				7. Total score	6.08	6.17	4.75	4.42	3.00	2.83	3.00
				1. ANXIETY/SOMATIZATION	1.50	1.50	1.00	1.00	0.67	0.50	0.67
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.33	0.17	0.00	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
454	454	Reboxetine	Male	5. RETARDATION	2.25	2.25	1.50	1.50	0.75	1.00	0.50
				6. SLEEP DISTURBANCE	1.00	1.00	1.33	1.00	0.67	0.67	1.00
				7. Total score	7.08	6.92	3.93	3.00	1.92	1.75	2.17
				1. ANXIETY/SOMATIZATION	1.50	1.50	0.33	0.33	0.33	0.33	0.50
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.33	0.17	0.17	0.17	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	0.00	0.00	0.00	0.00	0.00
455	455	Placebo	Female	5. RETARDATION	2.25	2.25	1.50	1.50	0.75	1.00	0.50
				6. SLEEP DISTURBANCE	1.00	1.00	1.33	1.00	0.67	0.67	1.00
				7. Total score	7.08	6.92	3.93	3.00	1.92	1.75	2.17
				1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.83	0.67	1.17	1.17

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PHARMACIA CNS RD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	455	Placebo	Female	2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.50	0.67	0.50	0.33	0.17	0.17
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	0.00	0.00
				5.REYARDATION	3.00	3.00	2.75	2.50	2.00	2.25	1.50
				6.SLEEP DISTURBANCE	0.33	0.33	0.33	0.67	0.33	0.33	0.33
				7.Total score	7.00	6.83	6.75	6.17	4.67	3.92	3.17
	456	Imipramine	Female	1.ANKIETY/SOMATIZATION	0.83	1.00	0.67	1.33			
				2.WEIGHT	1.00	0.00	0.00	0.00			
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.33			
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00			
				5.REYARDATION	2.75	2.75	2.25	2.25			
				6.SLEEP DISTURBANCE	1.33	1.33	1.00	0.00			
				7.Total score	6.42	5.58	4.25	3.92			
3/2	65/A	Reboxetine	Female	1.ANKIETY/SOMATIZATION	1.50	1.50	1.33	0.83	0.83	0.50	0.83
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.33	1.17	1.00	0.67	0.83	0.67	0.67
				4.DIURNAL VARIATION	0.00	2.00	1.00	0.00	1.00	1.00	0.00
				5.REYARDATION	1.25	1.50	1.25	1.00	1.50	1.75	1.50
				6.SLEEP DISTURBANCE	1.67	0.33	1.67	1.33	0.67	0.67	1.00
				7.Total score	5.75	6.50	8.25	3.83	4.83	4.58	4.00
3/3	67	Placebo	Male	1.ANKIETY/SOMATIZATION	1.33	1.00	1.00	1.00	0.50	0.67	0.50
				2.WEIGHT	1.00	0.00	1.00	0.00	0.00	2.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.67	0.33	0.83	0.17	0.00	0.17
				4.DIURNAL VARIATION	2.00	2.00	1.00	2.00	1.00	0.00	0.00
				5.REYARDATION	2.25	2.25	2.25	2.25	1.25	1.25	1.00
				6.SLEEP DISTURBANCE	1.00	1.33	0.00	1.00	0.67	0.67	0.67
				7.Total score	8.42	7.25	5.58	7.08	3.83	4.58	3.33
	68	Reboxetine	Male	1.ANKIETY/SOMATIZATION	0.83	1.00	0.67	0.33	0.17	0.00	0.00
				2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.33	0.33	0.00	0.00	0.00
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.REYARDATION	2.25	2.50	1.75	1.00	0.25	0.00	0.00
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.33	0.33	0.33	0.00
				7.Total score	6.75	5.17	3.42	2.00	0.75	0.33	0.00
	69	Placebo	Male	1.ANKIETY/SOMATIZATION	1.67	1.33	1.50	1.00	0.83	1.33	0.33
				2.WEIGHT	1.00	0.00	0.00	1.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.33	1.00	2.00	1.00	0.50	1.50	0.67
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.REYARDATION	2.50	2.25	2.50	1.50	0.75	2.50	1.25
				6.SLEEP DISTURBANCE	1.33	0.67	1.00	0.67	0.33	1.33	0.33
				7.Total score	7.83	5.25	7.00	5.17	2.42	6.67	2.58

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PIARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
3/3	70	Imipramine	Male	1. ANXIETY/SOMATIZATION	2.33	1.83	1.00	0.83	0.67	0.83	0.50	0.50	
				2. WEIGHT	1.00	2.00	1.00	0.00	1.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.17	1.00	1.00	0.67	0.33	0.50	0.17	0.17	0.17
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.25	1.75	1.25	1.00	0.25	0.50	0.50	0.50	0.50
				6. SLEEP DISTURBANCE	1.67	1.67	1.00	0.67	0.67	1.00	0.67	0.67	0.67
				7. Total score	8.42	8.25	5.25	3.17	2.92	2.83	1.83	1.83	1.83
				71	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.67	1.50	1.33	0.83	0.50	0.33
2. WEIGHT	0.00	0.00	0.00				0.00	0.00	0.00	0.00	0.00	0.00	
3. COGNITIVE DISTURBANCE	1.17	1.00	0.67				0.67	0.50	0.50	0.50	0.33	0.33	
4. DIURNAL VARIATION	0.00	0.00	0.00				0.00	0.00	0.00	0.00	0.00	0.00	
5. RETARDATION	2.25	2.00	1.25				0.75	0.50	0.50	0.25	0.25	0.25	
6. SLEEP DISTURBANCE	0.00	0.00	0.00				0.00	0.00	0.00	0.00	0.00	0.00	
7. Total score	5.08	4.50	3.25				2.25	1.50	1.33	0.92	0.75	0.75	
1/2 3/4	72	Reboxetine	Male				1. ANXIETY/SOMATIZATION	1.17	1.00	0.17	0.50	0.50	0.33
				2. WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.00
				3. COGNITIVE DISTURBANCE	1.33	0.83	0.83	0.50	0.33	0.33	0.17	0.33	0.33
				4. DIURNAL VARIATION	2.00	2.00	2.00	1.00	0.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.00	1.75	1.00	0.75	0.50	0.50	0.50	0.50	0.50
				6. SLEEP DISTURBANCE	1.33	0.67	0.33	0.00	0.00	0.33	0.00	0.67	0.67
				7. Total score	9.83	6.25	4.33	2.75	1.33	2.50	1.83	5.00	5.00
				3/4	79	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.50	1.00
2. WEIGHT	2.00	2.00	3.00					0.00	0.00	0.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	0.33	0.33	0.17					0.17	0.33	0.00	0.00	0.00	0.00
4. DIURNAL VARIATION	1.00	1.00	1.00					1.00	1.00	0.00	0.00	0.00	0.00
5. RETARDATION	2.50	2.50	1.75					1.50	0.75	0.00	0.00	0.00	0.00
6. SLEEP DISTURBANCE	1.33	1.33	1.00					1.00	0.33	0.33	0.33	0.33	0.33
7. Total score	8.83	8.83	8.42					5.17	3.42	0.83	0.67	0.67	0.67
80	Imipramine	Male	1. ANXIETY/SOMATIZATION					1.33	1.33	1.17	0.83	0.67	0.67
			2. WEIGHT	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.17	0.17	0.17	0.17	0.17		
			4. DIURNAL VARIATION	1.00	2.00	2.00	2.00	2.00	0.00	0.00	0.00		
			5. RETARDATION	1.50	1.50	1.50	1.00	1.00	0.75	0.75	0.75		
			6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	0.67	0.67	0.67	0.67		
			7. Total score	5.50	7.50	6.00	4.67	2.25	2.25	2.25	2.25		
			81	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	0.83	0.33	0.17	0.17	0.17
2. WEIGHT	2.00	2.00				0.00	0.00	0.00	0.00	0.00	0.00		
3. COGNITIVE DISTURBANCE	0.83	0.67				0.17	0.00	0.00	0.17	0.17	0.17		
4. DIURNAL VARIATION	0.00	0.00				0.00	0.00	0.00	0.00	0.00	0.00		
5. RETARDATION	2.50	2.50				1.25	0.50	0.25	0.25	0.25	0.25		

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

Centre	Patient	Treatment	Sex	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE								
				Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
3/4	81	Reboxetine	Female	1.67	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				8.17	8.33	2.25	0.83	0.42	1.08	1.08	0.58	0.58
				Hamilton depression rating scale								
				6.SLEEP DISTURBANCE								
				7.Total score								
	82	Placebo	Male	1.00	1.00	0.83	0.50	0.50	0.50	0.50	0.50	0.50
				0.00	0.00	0.00	1.00	1.00	0.00	0.00	0.00	0.00
				1.00	1.00	0.83	0.56	0.17	0.17	0.17	0.17	0.17
				1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				1.50	1.50	1.25	0.75	0.75	0.75	0.75	0.75	0.75
				1.33	1.33	1.00	0.33	0.33	0.33	0.33	0.33	0.33
				5.83	5.83	4.92	3.75	2.75	1.75	1.75	2.08	2.08
				7.Total score								
	83	Placebo	Male	1.17	1.17	1.67						
				0.00	0.00	0.00						
				0.83	0.83	1.17						
				1.00	1.00	2.00						
				1.75	1.75	1.25						
				1.00	1.00	1.67						
				5.75	5.75	8.25						
				7.Total score								
	84	Reboxetine	Female	1.50	1.50	0.83	0.93	0.17	0.17	0.17	0.17	0.17
				1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				0.33	0.33	0.17	0.17	0.00	0.00	0.00	0.00	0.00
				1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				1.75	1.75	1.25	0.75	0.50	0.50	0.25	0.25	0.25
				1.33	1.33	1.00	0.33	0.00	0.00	0.00	0.00	0.00
				6.92	6.92	4.85	1.58	0.67	0.67	0.42	0.42	0.42
				7.Total score								
	85	Imipramine	Female	1.33	1.33	1.00	0.50	0.67	0.83	0.50	0.50	0.17
				1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				0.83	0.83	0.50	0.33	0.17	0.50	0.17	0.00	0.00
				1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				2.25	2.25	1.75	1.50	1.25	1.25	1.00	0.75	0.75
				1.33	1.33	1.00	0.00	0.00	1.33	0.67	0.00	0.00
				7.75	6.75	5.25	2.33	2.08	3.92	2.33	0.92	0.92
				7.Total score								
	86	Imipramine	Male	1.33	1.33	1.00	0.67	0.50	0.33	0.50	0.50	0.50
				0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				1.00	1.00	0.33	0.17	0.80	0.00	0.00	0.00	0.00
				2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				2.25	2.25	1.50	0.75	0.75	0.50	0.50	0.50	0.50
				1.00	1.00	1.00	0.33	0.00	0.00	0.00	0.00	0.00
				7.58	7.58	5.83	1.92	1.25	0.83	1.00	1.00	1.00
				7.Total score								
	87	Placebo	Female	1.00	1.00	1.00	0.83	0.67	1.33	0.83	0.83	0.83
				0.00	0.00	0.00	0.00	0.00	0.00	1.00	1.00	0.00
				1.00	1.00	0.83	0.67	0.67	1.17	0.67	0.67	0.33
				3.COGNITIVE DISTURBANCE								

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PHARMACIA CNS RD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
3/4	87	Female	Placebo	1.00	1.00	1.00	0.00	0.00	0.00	0.00	
				4. DIURNAL VARIATION	1.75	1.75	1.50	1.25	1.00	2.00	1.25
				5. RETARDATION	1.33	1.33	1.00	0.33	0.00	1.00	0.33
				6. SLEEP DISTURBANCE	6.08	6.08	5.33	3.08	2.33	6.50	4.08
				7. Total score							
				1.83	1.83	1.50	1.17	0.83	0.83	0.83	0.67
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	0.33	0.33	0.17	0.17	0.00	0.00	0.00				
4. DIURNAL VARIATION	1.00	2.00	2.00	2.00	2.00	0.00	0.00				
5. RETARDATION	1.75	1.75	1.25	1.00	1.00	0.75	0.50				
6. SLEEP DISTURBANCE	1.33	1.33	0.67	0.00	0.00	0.00	0.00				
7. Total score	6.25	7.25	5.58	4.33	3.83	1.58	1.33				
89	Reboxetine	Female	Placebo	1.33	1.33	1.17	1.00	1.17	1.00	0.67	
				2. WEIGHT	2.00	2.00	1.00	0.00	1.00	1.00	0.00
				3. COGNITIVE DISTURBANCE	0.33	0.33	0.17	0.17	0.17	0.17	0.17
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	0.00
				5. RETARDATION	1.75	2.50	2.00	2.00	1.25	1.25	1.00
				6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.33	1.33	1.00	0.67
				7. Total score	8.08	8.83	6.67	5.50	5.92	5.75	2.83
90	Reboxetine	Male	Placebo	1.17	1.17	1.17	0.67	0.67	0.50	0.17	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.67	0.50	0.33	0.00
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00
				5. RETARDATION	1.75	1.75	1.75	1.50	1.50	0.75	0.25
				6. SLEEP DISTURBANCE	1.00	1.00	1.00	0.33	0.00	0.33	0.33
				7. Total score	5.92	5.92	5.92	4.17	2.67	1.92	0.75
457	Placebo	Female	Placebo	1.33	1.33	1.33	1.33	1.33	1.33	1.33	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.83	0.67	0.83	0.67	0.83
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.75	2.50	2.75	2.50	2.50	2.50	2.50
				6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.67	1.67	1.67
				7. Total score	6.42	6.17	7.58	6.17	6.33	6.33	6.33
458	Reboxetine	Female	Placebo	2.33	2.33	2.33	2.33	2.33	2.33	2.33	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	1.17	1.17	1.17	1.17
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.00	1.75	2.00	2.00	2.25	2.25	2.25
				6. SLEEP DISTURBANCE	0.67	0.67	1.00	1.00	1.00	1.00	1.00
				7. Total score	5.67	5.42	6.00	6.00	6.75	6.75	6.75
459	Placebo	Female	Placebo	1.67	1.67	1.33	1.33	1.33	1.00	0.83	
				1. ANXIETY/SOMATIZATION							

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17

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PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
3/4	459	Placebo	Female	2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.50	0.17	0.17	0.00	
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				5.RETARDATION	2.00	2.00	1.50	1.25	1.00	1.00	0.75	
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	0.33	0.00	0.00	
				7.Total score	6.33	6.33	4.00	3.75	3.17	2.17	1.58	
				1.ANXIETY/SOMATIZATION	1.67	1.67	1.67					
				2.WEIGHT	2.00	2.00	0.00					
461	461	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.50					
				2.WEIGHT	0.00	0.00	0.00					
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.33					
				4.DIURNAL VARIATION	1.00	1.00	1.00					
				5.RETARDATION	1.50	1.50	1.25					
				6.SLEEP DISTURBANCE	2.00	2.00	1.67					
				7.Total score	8.50	8.50	5.92					
				1.ANXIETY/SOMATIZATION	1.33	1.33	1.50					
2.WEIGHT	0.00	0.00	0.00									
3.COGNITIVE DISTURBANCE	0.33	0.33	0.33									
4.DIURNAL VARIATION	1.00	1.00	1.00									
5.RETARDATION	2.00	2.00	1.50									
6.SLEEP DISTURBANCE	1.67	1.67	1.67									
7.Total score	6.33	6.33	6.00									
462	462	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00					
				2.WEIGHT	1.00	1.00	0.00					
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.17					
				4.DIURNAL VARIATION	1.00	1.00	1.00					
				5.RETARDATION	2.00	2.00	1.00					
				6.SLEEP DISTURBANCE	1.33	1.33	1.33					
				7.Total score	6.67	6.67	4.50					
				1.ANXIETY/SOMATIZATION	1.00	1.00	1.00					
2.WEIGHT	0.00	0.00	0.00									
3.COGNITIVE DISTURBANCE	0.50	0.50	0.83									
4.DIURNAL VARIATION	1.00	1.00	1.00									
5.RETARDATION	1.75	1.75	2.00									
6.SLEEP DISTURBANCE	2.00	2.00	0.67									
7.Total score	7.00	6.92	6.85									
4/1	91	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.83	1.67	1.33					
				2.WEIGHT	0.00	0.00	1.00					
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.17					
				4.DIURNAL VARIATION	1.00	1.00	1.00					
				5.RETARDATION	1.75	1.75	1.00					
				6.SLEEP DISTURBANCE	2.00	2.00	1.00					
				7.Total score	7.08	6.92	5.17					
				1.ANXIETY/SOMATIZATION	1.83	1.67	1.33					
2.WEIGHT	0.00	0.00	1.00									
3.COGNITIVE DISTURBANCE	0.50	0.50	0.17									
4.DIURNAL VARIATION	1.00	1.00	1.00									
5.RETARDATION	1.75	1.75	1.00									
6.SLEEP DISTURBANCE	2.00	2.00	1.00									
7.Total score	7.08	6.92	5.17									
92	92	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50					
				2.WEIGHT	1.00	1.00	0.00					
				3.COGNITIVE DISTURBANCE	1.67	1.67	1.67					
				4.DIURNAL VARIATION	0.00	0.00	0.00					
				5.RETARDATION	2.75	2.75	3.00					
				6.SLEEP DISTURBANCE	2.00	2.00	2.00					
				7.Total score	8.92	8.92	8.17					
				1.ANXIETY/SOMATIZATION	1.50	1.50	1.50					
2.WEIGHT	1.00	1.00	0.00									
3.COGNITIVE DISTURBANCE	1.67	1.67	1.67									
4.DIURNAL VARIATION	0.00	0.00	0.00									
5.RETARDATION	2.75	2.75	3.00									
6.SLEEP DISTURBANCE	2.00	2.00	2.00									
7.Total score	8.92	8.92	8.17									

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18

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
4/1	93	Male	Placebo	1.ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.67	1.00	0.17	0.17	0.00	
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.17	1.17	1.00	1.67	0.67	0.17	0.17	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	1.75	2.25	1.50	0.75	0.75	0.25	0.25
				6.SLEEP DISTURBANCE	1.67	1.67	1.33	1.67	1.00	0.33	0.33	0.00	0.00
				7.Total score	7.17	7.17	7.25	9.25	6.17	1.42	1.42	0.25	0.25
94	Female	Placebo	1.ANXIETY/SOMATIZATION	2.17	2.17	2.00	0.83	0.33	0.17	0.17	0.17	0.00	
			2.WEIGHT	1.00	1.00	2.00	1.00	1.00	2.00	2.00	2.00	2.00	
			3.COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.17	0.00	0.00	0.00	0.00	0.00	
			4.DIURNAL VARIATION	0.00	0.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.00	2.00	1.00	1.00	1.00	0.25	0.25	0.00	0.00	
			6.SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.00	0.00	0.00	0.00	0.00	
			7.Total score	7.50	7.50	9.17	4.67	2.33	2.42	2.17	2.17	2.17	
95	Female	Imipramine	1.ANXIETY/SOMATIZATION	1.17	1.17	0.17	0.00	0.00	0.00	0.17	0.00	0.00	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.17	0.17	0.17	0.17	0.17	0.00	0.00	
			4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.00	2.00	0.75	0.50	0.50	0.50	0.75	0.75	0.00	
			6.SLEEP DISTURBANCE	1.33	1.33	0.33	0.33	0.33	0.33	0.33	0.33	0.00	
			7.Total score	6.17	6.17	1.42	1.00	1.00	1.00	1.42	0.00	0.00	
96	Female	Reboxetine	1.ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.17	1.00	0.67	0.83	0.83	0.00	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.67	1.67	1.33	1.17	0.67	0.67	0.67	0.50	0.50	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.75	2.75	2.00	1.75	1.00	1.00	1.00	1.00	1.00	
			6.SLEEP DISTURBANCE	2.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			7.Total score	7.92	7.92	5.67	5.08	3.67	3.33	3.50	3.33	3.33	
115	Female	Reboxetine	1.ANXIETY/SOMATIZATION	1.83	1.67	1.50	1.17	1.00	1.00	1.00	0.67	0.67	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.17	1.17	0.50	0.50	0.50	0.50	0.50	0.50	0.50	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.75	2.75	2.50	2.25	1.75	1.50	1.25	1.25	1.25	
			6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.00	1.00	1.00	0.67	0.67	0.67	
			7.Total score	7.42	7.25	6.17	4.92	5.25	5.00	4.42	4.08	4.08	
116	Female	Imipramine	1.ANXIETY/SOMATIZATION	1.67	1.33	1.67							
			2.WEIGHT	0.00	0.00	0.00							
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00							
			4.DIURNAL VARIATION	0.00	0.00	0.00							
			5.RETARDATION	2.75	2.75	2.75							

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19

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	116	Imipramine	Female	6.SLEEP DISTURBANCE 7.Total score	1.00 6.42	0.67 5.75	1.00 6.42				
	117	Imipramine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 2.00 3.00 2.00 2.00 10.50	1.50 0.00 2.00 3.00 2.00 2.00 10.50	1.17 0.00 1.17 1.00 2.00 1.00 6.33	0.83 0.00 0.50 1.00 1.50 0.33 4.17	0.50 0.00 0.33 0.00 0.50 0.33 2.17	0.50 0.00 0.33 0.00 0.50 0.33 1.67	0.50 0.00 0.33 0.00 0.50 0.33 2.00
	118	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.67 0.00 0.67 0.00 2.25 1.00 5.58	1.33 1.00 0.83 2.00 2.00 1.33 8.50	1.17 1.00 0.83 2.00 2.00 1.00 8.33	0.83 0.00 0.50 1.00 1.25 0.33 5.17	0.67 0.00 0.17 0.00 1.00 0.33 2.75	0.50 0.00 0.17 0.00 1.00 0.33 2.00	0.50 0.00 0.17 0.00 1.00 0.33 2.00
	119	Placebo	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 1.00 0.67 1.00 1.75 1.33 7.58	1.83 1.00 0.67 1.00 1.75 1.33 7.58					
	120	Placebo	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 0.83 0.00 1.75 1.00 5.08	1.50 0.00 0.50 0.00 1.75 1.00 4.75	1.17 1.00 0.33 0.00 1.25 0.67 5.08	1.17 1.00 0.17 0.00 1.25 0.33 4.08	1.00 1.00 0.17 0.00 1.25 0.67 3.75	0.50 1.00 0.17 0.00 1.25 0.67 3.58	0.50 1.00 0.17 0.00 1.00 0.67 3.33
	145	Imipramine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 1.67 0.00 2.50 2.00 7.67	1.50 0.00 1.67 0.00 2.50 1.67 7.67	1.17 0.00 0.83 0.00 1.75 1.00 4.75	0.83 0.00 0.50 0.00 1.25 0.67 3.25	0.83 0.00 0.50 0.00 1.25 0.67 3.25	0.83 0.00 0.50 0.00 1.00 0.67 3.00	0.83 0.00 0.50 0.00 1.00 0.67 2.33
	146	Placebo	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE	1.67 1.00 0.67	1.67 1.00 0.67	1.00 1.00 0.67	1.00 1.00 0.50	1.00 1.00 0.50	0.67 0.67 0.50	0.67 0.67 0.50

1269

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20

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	146	Placebo	Female	4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.00	2.00	2.00	1.00	1.25	1.00	1.00
				6. SLEEP DISTURBANCE	1.67	1.67	1.00	0.33	0.33	0.33	0.00
				7. Total score	7.00	7.00	5.67	4.83	3.83	2.75	2.50
				1. ANXIETY/SOMATIZATION	1.83	1.83	1.67	1.00	1.00	1.00	1.17
				2. HEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.50	0.50	0.50	0.50
147	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
			5. RETARDATION	2.50	2.50	2.00	1.75	1.50	1.25	1.00	
			6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.67	1.33	1.00	1.00	
			7. Total score	8.50	7.50	6.83	7.00	5.92	5.33	4.92	
			1. ANXIETY/SOMATIZATION	1.33	1.17	1.33	1.33	1.00	1.00	0.83	
			2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.67	0.67	0.67	0.50	
148	Imipramine	Female	4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	2.25	2.25	1.50	1.25	1.00	1.00	1.00	
			6. SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	0.67	
			7. Total score	5.75	5.58	4.67	4.25	3.67	3.67	2.67	
			1. ANXIETY/SOMATIZATION	1.33	1.17	1.33	1.33	1.00	1.00	0.83	
			2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.67	0.67	0.67	0.50	
149	Reboxetine	Male	4. DIURNAL VARIATION	1.50	1.50	1.67	1.00	1.33	0.83	0.83	0.83
			5. RETARDATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			6. SLEEP DISTURBANCE	0.83	0.83	0.67	0.67	0.50	0.50	0.50	
			7. Total score	2.25	2.25	2.50	2.00	1.75	1.25	1.00	
			1. ANXIETY/SOMATIZATION	1.00	1.00	0.67	0.67	0.67	0.33	0.33	
			2. HEIGHT	5.58	5.58	5.50	4.33	4.25	2.92	2.67	
			3. COGNITIVE DISTURBANCE	1.33	1.33	1.00	0.83	0.67	0.67	0.50	
150	Placebo	Male	4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	1.17	1.17	1.00	0.67	0.67	0.67	0.67	
			6. SLEEP DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			7. Total score	2.25	2.25	1.75	1.50	1.00	1.00	1.00	
			1. ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.67	0.67	0.67	0.67	
			2. HEIGHT	5.42	5.42	4.42	3.67	3.00	3.00	2.83	
			3. COGNITIVE DISTURBANCE	1.33	1.33	1.00	0.83	0.67	0.67	0.50	
4/2	93/A	Placebo	Male	4. DIURNAL VARIATION	1.67	1.67	1.83	1.67	1.33	0.50	0.33
				5. RETARDATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00
				6. SLEEP DISTURBANCE	0.83	0.83	0.83	0.67	0.50	0.00	0.00
				7. Total score	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				1. ANXIETY/SOMATIZATION	2.75	2.75	2.75	1.50	0.75	0.50	0.00
				2. HEIGHT	2.00	2.00	2.00	2.00	1.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	8.25	8.25	8.42	8.08	4.83	1.25	0.83
99/A	Placebo	Male	4. DIURNAL VARIATION	1.67	1.67	1.67	1.17	1.17	0.83	0.50	0.33
			5. RETARDATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00	
			6. SLEEP DISTURBANCE	0.83	0.83	0.83	0.67	0.50	0.00	0.00	
			7. Total score	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			1. ANXIETY/SOMATIZATION	2.75	2.75	2.75	1.50	0.75	0.50	0.00	
			2. HEIGHT	2.00	2.00	2.00	2.00	1.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	8.25	8.25	8.42	8.08	4.83	1.25	0.83	

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21

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

Centre	Patient Treatment	Sex	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE								
			Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
4/2	99/A	Male	2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.50	0.33	0.00	0.00	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.50	2.50	1.75	1.75	1.00	0.25	0.00	
			6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.67	0.67	0.00	0.00	
			7.Total score	6.50	6.50	4.08	4.08	2.83	0.75	0.33	
				1.50	1.50	1.50	1.33	1.33	1.33	1.33	
104	Reboxetine	Male	1.ANKIETY/SOMATIZATION	2.00	2.00	3.00	3.00	0.00	0.00	0.00	
			2.WEIGHT	1.50	1.50	1.00	1.00	1.00	1.00	1.00	
			3.COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			4.DIURNAL VARIATION	2.50	2.50	2.25	1.75	1.75	1.75	1.75	
			5.RETARDATION	1.67	1.67	1.67	1.67	1.67	1.67	1.67	
			6.SLEEP DISTURBANCE	9.17	9.17	10.17	9.42	5.75	5.75	5.75	
			7.Total score	1.50	1.50	1.50	1.50	2.00	2.00	2.00	
4/3	97	Male	1.ANKIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			2.WEIGHT	0.67	0.67	0.50	0.50	0.67	0.67	0.67	
			3.COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			4.DIURNAL VARIATION	1.75	2.00	2.00	2.00	2.00	2.00	2.00	
			5.RETARDATION	1.33	1.33	1.67	1.67	1.67	1.67	1.67	
			6.SLEEP DISTURBANCE	5.25	5.83	5.67	5.67	5.67	5.67	5.67	
			7.Total score	1.67	1.67	1.33	1.50	1.17	1.17	1.83	
98	Reboxetine	Female	1.ANKIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			2.WEIGHT	0.83	0.83	0.83	0.83	0.83	0.83	0.83	
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			4.DIURNAL VARIATION	1.50	1.50	2.00	2.00	1.50	2.00	2.00	
			5.RETARDATION	1.00	1.00	2.00	2.00	1.00	2.00	2.00	
			6.SLEEP DISTURBANCE	6.00	6.00	7.17	10.33	5.50	5.50	6.67	
			7.Total score	1.50	1.50	1.50	2.17	0.00	0.00		
99	Placebo	Female	1.ANKIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00		
			2.WEIGHT	0.67	0.67	0.67	0.83	0.83	0.83		
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00		
			4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00		
			5.RETARDATION	2.00	2.00	2.00	2.00	2.00	2.00		
			6.SLEEP DISTURBANCE	7.17	7.17	7.17	8.00	8.00	8.00		
			7.Total score	1.17	1.33	1.33	1.67	1.67	1.67		
100	Imipramine	Female	1.ANKIETY/SOMATIZATION	2.00	2.00	1.00	1.00	1.00	1.00		
			2.WEIGHT	0.83	0.83	0.50	0.83	0.83	0.83		
			3.COGNITIVE DISTURBANCE	1.00	1.00	0.00	0.00	0.00	0.00		
			4.DIURNAL VARIATION	1.50	2.00	1.75	1.75	1.75	1.75		
			5.RETARDATION	1.67	1.67	1.33	1.33	1.33	1.33		
			6.SLEEP DISTURBANCE	8.17	8.50	5.92	6.58	6.58	6.58		
			7.Total score	1.17	1.33	1.33	1.67	1.67	1.67		

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/3	101	Imipramine	Male	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	1.50	1.50	1.33	0.83	0.50	0.33	0.00
				Hamilton depression rating scale	0.00	0.00	0.00	0.00	0.00	0.00	
				1. ANXIETY/SOMATIZATION	0.83	0.83	1.00	0.33	0.17	0.00	
				2. WEIGHT	2.00	2.00	1.00	0.00	1.00	0.00	
				3. COGNITIVE DISTURBANCE	2.00	2.00	2.25	1.50	1.00	0.75	
				4. DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.33	0.00	
				5. RETARDATION	7.33	7.33	7.75	5.67	2.17	1.25	
				7. Total score	1.17	1.33	1.17	0.83	0.50	0.33	
4/4	109	Reboxetine	Female	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				Hamilton depression rating scale	0.67	0.83	0.33	0.17	0.17	0.00	
				1. ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	
				2. WEIGHT	2.00	2.00	1.50	1.25	0.75	0.50	
				3. COGNITIVE DISTURBANCE	2.00	1.33	1.00	0.67	0.33	0.17	
				4. DIURNAL VARIATION	7.83	5.50	4.00	2.92	1.75	1.50	
				5. RETARDATION	1.50	1.17	0.83	0.50	0.33	0.17	
				7. Total score	1.50	1.17	0.83	0.50	0.33	0.17	
110	1272	Imipramine	Male	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	2.00	2.00	0.83	1.17	0.67	0.33	0.50
				Hamilton depression rating scale	0.17	0.50	0.33	0.17	0.17	0.17	
				1. ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	
				2. WEIGHT	2.00	2.50	1.75	1.75	1.25	1.00	
				3. COGNITIVE DISTURBANCE	2.00	1.67	1.33	1.33	0.67	0.33	
				4. DIURNAL VARIATION	7.67	7.83	4.25	4.58	2.75	1.83	
				5. RETARDATION	1.50	1.17	1.00	0.67	0.50	0.33	
				7. Total score	2.00	0.00	0.00	0.00	0.00	0.00	
111		Imipramine	Male	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	1.50	1.17	1.00	0.67	0.50	0.33	0.33
				Hamilton depression rating scale	2.00	0.50	0.50	0.17	0.00	0.00	
				1. ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	
				2. WEIGHT	2.25	2.25	2.25	1.50	1.25	1.00	
				3. COGNITIVE DISTURBANCE	1.67	2.00	1.67	1.00	0.33	0.00	
				4. DIURNAL VARIATION	7.92	5.92	5.42	3.33	2.25	1.83	
				5. RETARDATION	1.50	1.17	1.00	0.67	0.50	0.33	
				7. Total score	1.33	0.83	0.83	0.67	0.50	0.33	
112		Placebo	Male	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	2.00	0.33	0.17	0.17	0.00	0.17	0.17
				Hamilton depression rating scale	0.00	0.00	0.00	0.00	0.00	0.00	
				1. ANXIETY/SOMATIZATION	1.75	1.75	1.50	1.25	1.00	1.00	
				2. WEIGHT	2.00	1.67	1.00	0.67	0.67	0.67	
				3. COGNITIVE DISTURBANCE	7.42	5.08	3.50	2.92	2.50	2.17	
				4. DIURNAL VARIATION	1.00	1.17	1.33	0.83	0.83	0.67	
				5. RETARDATION	1.00	0.00	2.00	0.00	2.00	0.00	
				7. Total score	0.67	0.67	0.33	0.33	0.17	0.00	
113		Reboxetine	Male	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	2.25	2.00	2.00	1.75	1.00	0.75	0.25
				Hamilton depression rating scale	1.00	0.00	0.00	0.00	0.00	0.00	
				1. ANXIETY/SOMATIZATION	0.67	0.67	0.33	0.33	0.17	0.00	
				2. WEIGHT	0.00	1.00	1.00	0.00	0.00	0.00	
				5. RETARDATION	2.25	2.00	2.00	1.75	1.00	0.75	

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23

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
4/4	113	Male	6.SLEEP DISTURBANCE	2.00	1.67	1.33	1.00	1.00	0.33	0.33	
			7.Total score	6.92	6.50	7.33	4.25	5.25	2.83	1.58	0.92
114	Placebo	Female	1.ANXIETY/SOMATIZATION	1.67	1.83	1.67	1.33	1.00	1.00	0.83	0.83
			2.WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	0.50	0.67	0.50	0.17	0.17	0.00	0.00	0.00
			4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
			5.RETARDATION	2.25	2.25	2.00	1.50	1.00	1.00	0.75	0.75
			6.SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.67	0.33	0.33	0.33
			7.Total score	7.75	7.08	5.50	3.67	2.83	2.33	1.92	1.92
175	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.00	1.17	0.83	0.67	0.33	0.33
			2.WEIGHT	1.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.33	0.00	0.00	0.17	0.00
			4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
			5.RETARDATION	2.25	2.50	2.25	1.50	1.25	1.25	0.50	0.00
			6.SLEEP DISTURBANCE	1.33	1.67	1.33	1.00	0.67	0.33	0.33	0.33
			7.Total score	7.25	6.83	4.92	4.00	3.75	2.25	1.33	0.67
176	Placebo	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.33		
			2.WEIGHT	1.00	0.00	0.00	0.00	1.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.17	0.17	1.00		
			4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00		
			5.RETARDATION	2.00	2.00	1.75	1.50	1.50	2.50		
			6.SLEEP DISTURBANCE	1.67	1.33	1.00	1.00	0.67	1.00		
			7.Total score	7.17	5.83	5.25	3.67	4.33	5.83		
177	Imipramine	Female	1.ANXIETY/SOMATIZATION	2.00	2.17	2.00	2.00				
			2.WEIGHT	2.00	0.00	0.00	1.00				
			3.COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.17				
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00				
			5.RETARDATION	1.50	1.75	1.75	1.75				
			6.SLEEP DISTURBANCE	1.67	1.33	0.67	1.33				
			7.Total score	7.50	5.58	4.75	6.25				
178	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	0.67	0.33	0.33	0.17	
			2.WEIGHT	1.00	0.00	0.00	0.00	1.00	1.00	1.00	
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.17	0.00	0.00	0.00	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.00	2.00	1.50	1.00	1.00	0.50	0.25	
			6.SLEEP DISTURBANCE	1.67	1.33	1.00	0.33	0.33	0.33	0.67	
			7.Total score	6.67	5.33	3.83	2.17	2.67	1.17	1.92	
179	Placebo	Female	1.ANXIETY/SOMATIZATION	1.33	1.17	1.17	1.00	1.17			
			2.WEIGHT	1.00	0.00	1.00	0.00	1.00			
			3.COGNITIVE DISTURBANCE	0.83	0.50	0.50	0.33	1.17			

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24

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
4/4	179	Placebo	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00			
				5. RETARDATION	2.50	2.00	1.75	1.50	3.00			
				6. SLEEP DISTURBANCE	1.67	2.00	1.33	1.00	1.33			
				7. Total score	8.33	6.67	6.75	4.83	7.67			
180	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.00	0.67	0.67	0.33	0.00	0.17	
			2. WEIGHT	1.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.67	0.50	0.33	0.33	0.00	0.00	0.00	0.00	0.00
			4. DIURNAL VARIATION	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	2.25	2.50	2.00	1.25	1.00	0.75	0.50	0.50	0.50
			6. SLEEP DISTURBANCE	1.67	1.67	1.33	0.67	0.33	0.33	0.33	0.33	0.33
			7. Total score	6.75	6.83	4.67	2.92	3.00	1.42	0.83	1.00	
5/1	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.83	1.83	1.00	1.00	1.00	0.67	0.83	1.00	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.50	0.83	0.50	0.67	0.50	0.67
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00
			5. RETARDATION	3.00	3.00	2.25	2.00	1.75	2.50	1.75	1.50	1.50
			6. SLEEP DISTURBANCE	1.00	1.33	1.00	1.00	1.00	1.00	0.67	1.00	0.67
			7. Total score	7.53	7.67	5.58	5.50	4.58	5.50	4.75	5.17	
128	Reboxetine	Female	1. ANXIETY/SOMATIZATION	2.00	2.00	0.67	1.00	1.00	0.83	1.00	1.33	
			2. WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.00	1.00	0.50	0.50	0.50	0.50	0.67	0.67	
			4. DIURNAL VARIATION	1.00	2.00	1.00	2.00	1.00	1.00	0.00	0.00	
			5. RETARDATION	2.25	2.00	1.25	0.75	1.00	0.75	0.75	0.75	
			6. SLEEP DISTURBANCE	2.00	1.67	0.00	0.00	0.00	0.33	0.00	0.00	
			7. Total score	10.25	8.67	3.42	4.25	3.50	3.42	2.42	2.75	
129	Placebo	Male	1. ANXIETY/SOMATIZATION	0.67	0.67	0.50	0.67	0.50	0.33	0.50	1.17	
			2. WEIGHT	2.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.00	1.00	1.50	0.83	0.67	0.33	0.33	0.67	
			4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	1.00	0.00	
			5. RETARDATION	1.75	1.75	2.00	0.75	0.75	0.50	0.50	1.25	
			6. SLEEP DISTURBANCE	1.67	1.67	0.33	0.00	0.00	0.00	0.33	0.67	
			7. Total score	8.08	8.08	6.33	4.25	1.92	1.17	2.67	4.75	
130	Placebo	Male	1. ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.17	1.17	0.17	0.17	0.17	
			2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.33	1.33	0.67	0.33	1.00	0.17	0.00	0.17	
			4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	0.00	0.00	
			5. RETARDATION	2.50	2.50	1.00	1.75	1.00	0.75	0.75	1.00	
			6. SLEEP DISTURBANCE	0.67	0.67	0.00	0.67	0.33	1.67	1.00	0.00	
			7. Total score	9.17	9.17	5.08	4.17	5.25	3.75	1.75	2.33	
131	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	0.67	0.83	1.33	0.17	0.00	0.33	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

Centre	Patient	Treatment	Sex	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE																
				Hamilton depression rating scale																
				Screen	Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42		
5/1	131	Imipramine	Female	2.WEIGHT	0.00	0.00	0.00	0.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.50	0.50	0.33	0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.00	2.00	2.00	1.50	1.50	1.75	1.75	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
				6.SLEEP DISTURBANCE	1.67	1.67	1.00	1.00	1.00	0.67	1.33	0.67	1.33	0.67	1.33	0.67	1.33	0.67	1.33	0.67
				7.Total score	6.67	6.67	5.00	6.33	6.25	6.33	6.25	6.33	6.25	6.33	6.25	6.33	6.25	6.33	6.25	6.33
132		Imipramine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.25	2.25	2.00	2.00	2.25	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.67	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				7.Total score	6.25	6.25	6.25	6.67	6.25	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00
5/2	121	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.83	1.67	2.00	2.00	1.83	1.83	1.17	1.50	1.50	1.50	1.67	2.00	2.00			
				2.WEIGHT	2.00	0.00	1.00	1.00	1.00	1.00	0.00	2.00	2.00	0.00	0.00	2.00	2.00	2.00		
				3.COGNITIVE DISTURBANCE	1.33	1.33	1.17	1.00	0.83	0.83	0.33	0.33	0.50	0.50	0.83	0.83	0.50	0.83		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80		
				5.RETARDATION	2.75	2.75	2.25	2.25	2.75	1.50	1.25	1.50	1.25	1.50	1.25	1.50	1.25	1.50		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33		
				7.Total score	10.25	8.08	7.75	8.92	8.92	3.33	5.42	4.00	7.17	7.17	7.17	7.17	7.17			
125		Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	2.00	2.00	0.33	0.83	0.83	0.50	0.50	0.33	0.50					
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
				3.COGNITIVE DISTURBANCE	0.17	0.50	0.67	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
				5.RETARDATION	3.00	2.25	2.25	2.25	0.75	0.85	0.25	0.25	0.25	0.25	0.25					
				6.SLEEP DISTURBANCE	0.00	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67					
				7.Total score	4.83	5.08	5.58	1.75	1.75	1.42	1.08	2.08								
5/3	133	Placebo	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.50	1.50	1.50	1.50	1.50	1.50	1.50						
				2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00						
				3.COGNITIVE DISTURBANCE	0.67	0.67	1.17	1.33	1.33	1.33	1.33	1.33	1.33	1.33						
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00						
				5.RETARDATION	2.25	2.25	2.25	2.25	2.25	2.25	2.25	2.25	2.25	2.25						
				6.SLEEP DISTURBANCE	2.00	1.67	1.67	2.00	2.00	2.00	2.00	2.00	2.00	2.00						
				7.Total score	10.42	8.08	8.42	9.58	9.58	9.58	9.58	9.58								
134		Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.50	0.17	0.33	0.33	0.00	0.00	0.17						
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00						
				3.COGNITIVE DISTURBANCE	1.00	0.83	0.67	0.17	0.83	0.83	0.00	0.00	0.00	0.00						
				4.DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00						
				5.RETARDATION	2.25	2.25	2.00	2.00	1.25	1.25	1.00	1.00	1.00	1.00						
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00						
				7.Total score	8.92	8.75	7.17	2.83	6.42	2.00	2.00	2.00								

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27

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
6/1	152	Reboxetine	Female	6.SLEEP DISTURBANCE	1.33	1.67	2.00	2.00	1.33	1.67	1.33	1.00
				7.Total score	8.25	6.67	5.00	4.75	4.75	5.00	3.33	1.58
153	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.33	1.17	1.00	1.33	1.17	1.17	1.17	1.17
			2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.33	0.00	0.17	0.17	0.00	0.00
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5.RETARDATION	2.25	2.00	2.00	1.25	1.00	1.00	1.00	1.00	1.00
			6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	0.67	0.67	0.67	0.67
			7.Total score	6.58	6.00	4.83	3.58	3.33	3.00	3.00	3.00	2.83
154	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.00	1.17							
			2.WEIGHT	0.00	0.00							
			3.COGNITIVE DISTURBANCE	0.50	0.33							
			4.DIURNAL VARIATION	0.00	0.00							
			5.RETARDATION	2.25	2.25							
			6.SLEEP DISTURBANCE	1.67	1.67							
			7.Total score	5.42	5.42							
155	Placebo	Male	1.ANXIETY/SOMATIZATION	1.17	1.33	1.17	1.17	1.00	1.00	1.00	1.00	1.00
			2.WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.67	0.50	0.83	0.83	0.83	0.83
			4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
			5.RETARDATION	2.75	2.75	2.75	2.50	2.25	2.25	2.25	2.25	2.25
			6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.67	1.33	1.67	1.67	1.67	1.67
			7.Total score	8.58	7.75	7.08	7.00	6.08	6.75	6.75	6.75	6.75
156	Placebo	Female	1.ANXIETY/SOMATIZATION	1.50	1.33	1.17	0.83	0.83	0.83	0.83	0.50	0.83
			2.WEIGHT	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	0.50	0.67	0.50	0.33	0.17	0.00	0.00	0.00	0.17
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5.RETARDATION	2.00	2.25	2.50	1.50	1.25	0.50	1.00	1.00	1.00
			6.SLEEP DISTURBANCE	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.00
			7.Total score	6.33	6.58	5.50	3.00	2.58	1.67	1.50	1.50	2.00
6/2	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	1.17	1.17	1.17	1.17	1.17	1.17	1.00
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	1.33	1.00	0.83	0.50	0.50	0.67	0.50	0.50	0.50
			4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
			5.RETARDATION	2.00	2.00	2.00	1.25	1.25	1.25	1.25	1.25	1.00
			6.SLEEP DISTURBANCE	0.67	1.33	2.00	1.00	0.67	0.00	0.00	0.00	0.00
			7.Total score	6.67	7.00	7.00	4.92	4.58	4.08	3.92	3.50	3.50
158	Imipramine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	0.67	0.67	0.67	0.83	0.83	0.17	0.17
			2.WEIGHT	2.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.67	0.50	0.50	0.33	0.33	

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28

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
6/2	158	Imipramine	Female	4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	0.00	
				5. RETARDATION	1.75	1.75	1.50	1.50	1.25	0.50		
				6. SLEEP DISTURBANCE	1.33	1.33	0.00	0.00	0.00	0.00		
				7. Total score	8.58	8.58	7.42	5.83	3.67	3.42	0.89	
159	159	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.33	1.00	1.00	1.00	0.50	0.67	0.67	0.83
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	1.00	1.00	1.33	1.00	0.67	0.83	0.50	1.17
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00
				5. RETARDATION	2.25	2.25	2.25	2.00	2.00	1.50	1.50	1.75
				6. SLEEP DISTURBANCE	0.67	0.67	0.00	0.00	0.00	0.00	0.00	0.00
				7. Total score	7.25	6.92	6.58	6.00	5.17	4.00	3.67	4.75
160	160	Placebo	Male	1. ANXIETY/SOMATIZATION	1.33	1.33	0.67	0.67	0.33	0.33	0.33	1.33
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	1.50	1.50	0.67	0.67	0.67	0.67	1.00	
				4. DIURNAL VARIATION	2.00	2.00	0.00	0.00	0.00	1.00	1.00	2.00
				5. RETARDATION	2.25	2.50	0.75	1.00	1.25	1.25	2.00	
				6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	1.00	1.00	1.00	0.67
				7. Total score	8.08	8.33	2.75	2.75	6.00	4.25	4.25	7.00
161	161	Reboxetine	Female	1. ANXIETY/SOMATIZATION	0.83	0.83	1.33	1.00	1.33	1.33	1.33	
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.83	0.67	0.67	0.83	0.83	0.83	0.83	
				4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
				5. RETARDATION	2.00	2.00	2.00	1.25	1.25	1.25	1.25	
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	1.00	1.00	
				7. Total score	7.00	6.83	5.33	4.08	4.42	4.42	4.42	
162	162	Placebo	Male	1. ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.67	1.67	1.67	1.67	
				2. WEIGHT	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.83	0.83	0.83	0.83	
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				5. RETARDATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
				6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.67	1.67	1.67	
				7. Total score	8.17	8.17	8.17	8.17	8.17	8.17	8.17	
169	169	Imipramine	Female	1. ANXIETY/SOMATIZATION	2.17	2.33	0.50	2.50	2.50	2.50	2.50	
				2. WEIGHT	3.00	3.00	0.00	3.00	3.00	3.00	3.00	
				3. COGNITIVE DISTURBANCE	1.83	1.67	0.17	2.50	3.00	3.00	3.00	
				4. DIURNAL VARIATION	1.00	1.00	0.00	1.00	2.00	2.00	2.00	
				5. RETARDATION	3.25	3.25	0.00	3.25	3.25	3.25	3.25	
				6. SLEEP DISTURBANCE	2.00	2.00	0.33	2.00	2.00	2.00	2.00	
				7. Total score	13.25	13.25	1.00	14.25	15.92	15.92	15.92	
170	170	Placebo	Male	1. ANXIETY/SOMATIZATION	2.33	2.50	0.50					

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29

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/2	170	Placebo	Male	2.WEIGHT	3.00	3.00	0.00				
				3.COGNITIVE DISTURBANCE	2.50	2.50	1.00				
				4.DIURNAL VARIATION	2.00	2.00	1.00				
				5.RETARDATION	3.00	3.25	1.00				
				6.SLEEP DISTURBANCE	2.00	2.00	0.67				
				7.Total score	14.83	15.25	4.17				
					2.17	1.83	1.83	1.00	0.33	0.00	0.00
171	171	Imipramine	Female	1.ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				2.WEIGHT	2.33	2.00	1.83	0.33	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.75	2.00	2.00	1.25	0.00	0.00	0.00
				5.RETARDATION	1.33	1.33	1.00	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	9.58	7.17	7.00	3.58	0.33	0.00	0.00
				7.Total score	1.83	1.83	1.83	1.67	1.67	1.67	1.67
172	172	Reboxetine	Female	1.ANXIETY/SOMATIZATION	3.00	3.00	3.00	3.00	3.00	3.00	3.00
				2.WEIGHT	1.00	1.00	1.33	1.50	1.50	1.50	1.67
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				4.DIURNAL VARIATION	3.00	3.00	3.00	3.00	3.00	3.00	2.75
				5.RETARDATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				6.SLEEP DISTURBANCE	11.83	11.83	12.17	12.17	10.17	9.17	9.08
				7.Total score	2.17	2.00	2.00	2.00	2.00	2.17	1.17
173	173	Placebo	Male	1.ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	1.00
				2.WEIGHT	2.00	2.00	1.83	1.83	1.83	2.00	1.33
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				4.DIURNAL VARIATION	2.50	2.50	2.25	2.25	2.25	2.75	1.75
				5.RETARDATION	1.67	1.67	1.67	2.00	1.67	0.33	0.33
				6.SLEEP DISTURBANCE	9.33	9.17	8.75	9.08	10.58	6.58	7.00
				7.Total score	2.17	2.00	2.00	2.00	2.00	2.00	0.83
174	174	Reboxetine	Male	1.ANXIETY/SOMATIZATION	2.00	2.00	0.00	0.00	0.00	0.00	0.00
				2.WEIGHT	0.00	1.83	0.00	0.00	0.00	0.00	0.67
				3.COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	3.25	3.25	0.50	0.00	0.00	0.00	1.25
				5.RETARDATION	2.00	2.00	0.00	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	11.42	11.08	1.17	0.00	0.00	0.00	0.00
				7.Total score	2.00	2.00	2.00	2.00	2.00	2.00	2.75
6/3	163	Reboxetine	Male	1.ANXIETY/SOMATIZATION	2.00	2.00	2.00				
				2.WEIGHT	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83				
				4.DIURNAL VARIATION	1.00	1.00	1.00				
				5.RETARDATION	2.25	2.25	2.25				
				6.SLEEP DISTURBANCE	0.00	0.00	0.00				
				7.Total score	6.08	6.08	6.08				

1279

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30

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
6/3	164	Imipramine	Male	1. ANXIETY/SOMATIZATION	2.00	2.00	1.83	1.00	1.00	0.83	0.83	0.83	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.83	0.67	0.83	0.67	0.50	0.50	0.50
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.25	2.25	2.25	1.75	2.00	2.00	2.00	2.00	1.50
				6. SLEEP DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				7. Total score	6.75	6.75	6.92	5.42	4.83	3.50	3.33	2.83	2.83
				165	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.50	1.67	1.50	1.33	1.17	1.17
2. WEIGHT	2.00	2.00	0.00				0.00	0.00	0.00	0.00	0.00		
3. COGNITIVE DISTURBANCE	0.83	0.83	0.50				0.50	0.50	0.67	0.67	0.67		
4. DIURNAL VARIATION	2.00	2.00	2.00				2.00	2.00	2.00	2.00	1.00		
5. RETARDATION	1.75	2.00	1.75				2.00	2.00	1.50	1.75	1.25		
6. SLEEP DISTURBANCE	0.67	1.00	0.33				0.33	0.33	0.00	0.00	0.00		
7. Total score	8.75	9.50	6.08				6.17	6.00	5.33	5.42	3.75		
166	Reboxetine	Female	1. ANXIETY/SOMATIZATION				1.50	1.83	1.83				
			2. WEIGHT	0.00	0.00	0.00							
			3. COGNITIVE DISTURBANCE	0.67	0.67	1.17							
			4. DIURNAL VARIATION	2.00	2.00	2.00							
			5. RETARDATION	2.25	2.75	2.75							
			6. SLEEP DISTURBANCE	0.00	0.00	1.33							
			7. Total score	6.42	7.25	9.08							
			167	Placebo	Female	1. ANXIETY/SOMATIZATION	1.33	1.50	1.00	0.83	0.50	0.50	0.67
2. WEIGHT	0.00	0.00				0.00	0.00	0.00	0.00	0.00	0.00		
3. COGNITIVE DISTURBANCE	1.33	1.00				0.50	0.67	0.67	0.50	0.33	0.33		
4. DIURNAL VARIATION	2.00	2.00				2.00	2.00	2.00	1.00	0.00	1.00		
5. RETARDATION	1.75	1.50				2.00	1.50	2.00	1.25	0.75	1.00		
6. SLEEP DISTURBANCE	0.00	0.00				0.00	0.00	0.00	0.00	0.00	0.00		
7. Total score	6.42	6.00				5.50	5.00	5.17	3.25	1.75	3.00		
168	Placebo	Female				1. ANXIETY/SOMATIZATION	1.50	1.50	1.17	1.33	1.17	1.67	1.67
			2. WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00			
			3. COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.50	0.50	0.50	0.83			
			4. DIURNAL VARIATION	0.00	2.00	2.00	1.00	0.00	0.00	0.00			
			5. RETARDATION	2.25	2.50	2.25	2.25	2.25	2.25	2.25			
			6. SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.67	0.67	0.67			
			7. Total score	7.25	7.50	6.75	5.08	4.58	5.08	5.42			
			505	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.83	2.00	1.33	1.67			
2. WEIGHT	0.00	0.00				0.00	0.00						
3. COGNITIVE DISTURBANCE	0.50	0.67				0.67	0.50						
4. DIURNAL VARIATION	1.00	2.00				0.00	0.00						
5. RETARDATION	2.25	2.25				2.25	2.00						

1280

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31

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	505	Imipramine	Female	6.SLEEP DISTURBANCE 7.Total score	0.00 5.58	0.00 6.92	0.67 4.92	1.93 5.50			
	506	Placebo	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 2.00 0.50 2.00 2.00 0.67 8.67	1.50 0.00 0.50 2.00 2.00 1.00 7.00	1.50 0.00 0.50 2.00 2.00 2.00 5.75	1.17 0.00 0.67 2.00 2.00 2.00 4.83	1.17 0.83 0.00 0.50 0.00 1.50 7.42	1.17 0.00 0.33 1.00 1.25 0.67 4.42	1.17 0.00 0.33 0.00 1.25 1.33 4.58
	507	Imipramine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 0.00 0.83 2.00 1.75 0.33 6.25	1.33 0.00 0.83 2.00 1.75 0.33 6.25	1.33 0.00 0.33 1.00 1.25 0.90 4.25	1.33 0.00 0.67 1.00 1.25 0.90 4.25	0.83 0.00 0.17 0.00 1.00 0.60 2.25	0.50 0.00 0.17 0.00 0.25 0.00 1.25	0.17 0.00 0.17 0.00 0.50 0.00 0.83
	508	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	0.83 2.00 0.50 2.00 2.00 0.67 8.00	1.17 0.50 0.67 2.00 2.00 0.67 8.00	0.50 0.00 0.50 2.00 2.00 0.67 8.33	1.00 0.00 0.17 2.00 2.00 0.00 5.42	0.67 0.00 0.33 1.00 1.50 0.67 5.17	0.50 0.00 0.17 1.00 1.00 0.33 4.00	0.33 0.00 0.17 1.00 1.00 0.33 2.83
	509	Placebo	Male	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 0.50 2.00 2.00 0.33 6.08	0.00 0.00 0.67 2.00 2.00 0.33 5.50	0.83 0.00 0.50 2.00 2.00 0.67 3.25	0.83 0.00 0.67 1.25 1.25 0.00 2.75	1.33 0.00 0.33 1.00 1.25 0.33 4.50	0.83 0.00 0.33 1.00 1.25 0.00 3.42	0.50 0.00 0.33 1.00 1.25 0.00 3.75
	510	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 0.00 0.67 2.00 2.00 0.67 6.67	1.33 0.00 0.67 2.00 2.00 0.67 6.67	1.00 0.00 0.33 1.00 1.25 1.00 4.08	1.17 0.00 0.33 0.90 1.25 1.33 4.08	1.17 0.00 0.33 0.90 1.25 1.33 4.08	1.17 0.00 0.33 0.90 1.25 1.33 4.08	
	511	Imipramine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE	1.17 2.00 0.83	1.50 2.00 0.83	0.67 0.67 0.33	0.67 0.08 0.33	0.83 0.00 0.67	0.67 0.00 0.67	1.17 0.00 1.17

1281

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	511	Imipramine	Female	4. DIURNAL VARIATION	2.00	2.00	1.00	0.00	1.00	1.00	1.00
				5. RETARDATION	1.75	1.75	1.50	1.50	1.25	1.25	
				6. SLEEP DISTURBANCE	0.00	0.67	0.00	0.33	0.33	0.67	
				7. Total score	7.75	8.75	3.83	2.83	4.08	4.25	
				1. ANXIETY/SOMATIZATION	1.17	1.17	1.50				
				2. WEIGHT	0.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67				
512	Placebo	Female	4. DIURNAL VARIATION	2.00	2.00	2.00					
			5. RETARDATION	2.00	2.00	2.00					
			6. SLEEP DISTURBANCE	0.67	1.00	1.00					
			7. Total score	6.50	6.83	7.17					
			1. ANXIETY/SOMATIZATION	1.50	1.50	1.50					
			2. WEIGHT	0.00	0.00	0.00					
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67					
7/02	181	Reboxetine	Male	4. DIURNAL VARIATION	2.00	2.00	2.00				
				5. RETARDATION	1.75	1.75	1.25				
				6. SLEEP DISTURBANCE	1.00	1.00	0.67				
				7. Total score	6.92	6.92	5.58				
				1. ANXIETY/SOMATIZATION	1.50	1.50	1.00				
				2. WEIGHT	0.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67				
7/02	182	Placebo	Male	4. DIURNAL VARIATION	2.00	2.00	2.00				
				5. RETARDATION	2.00	2.00	2.00				
				6. SLEEP DISTURBANCE	0.67	0.67	0.67				
				7. Total score	5.67	5.67	5.92				
				1. ANXIETY/SOMATIZATION	1.50	1.50	1.50				
				2. WEIGHT	0.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.50				
7/02	183	Imipramine	Male	4. DIURNAL VARIATION	2.00	2.00	2.00				
				5. RETARDATION	1.25	1.25	1.25				
				6. SLEEP DISTURBANCE	1.67	1.67	2.00				
				7. Total score	5.92	5.92	6.58				
				1. ANXIETY/SOMATIZATION	1.50	1.50	1.33				
				2. WEIGHT	1.00	1.00	0.00				
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.33				
7/02	184	Imipramine	Female	4. DIURNAL VARIATION	2.00	2.00	2.00				
				5. RETARDATION	1.25	1.25	1.00				
				6. SLEEP DISTURBANCE	2.00	2.00	1.67				
				7. Total score	7.08	7.08	5.33				
				1. ANXIETY/SOMATIZATION	1.50	1.50	1.33				
				2. WEIGHT	1.00	1.00	0.00				
				3. COGNITIVE DISTURBANCE	0.53	0.53	0.33				

1.17 1.17 1.17 1.00 0.83 0.83 0.50 0.17

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33

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/02	184	Imipramine	Female	2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.17	0.17	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00
				5.RETARDATION	2.50	2.50	2.50	2.00	1.00	0.00	0.00
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.00	0.67	0.00	0.00
				7.Total score	6.83	6.83	6.83	5.67	2.67	1.25	0.67
185		Reboxetine	Male	1.ANKIETY/SOMATIZATION	1.67	1.67	1.50	1.50	0.83		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.67	0.67		
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	0.75	0.75	1.50	1.25	1.75		
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.67		
				7.Total score	4.92	4.92	5.67	5.08	4.92		
186		Placebo	Male	1.ANKIETY/SOMATIZATION	1.17	1.17	0.83	0.83	0.83	0.83	0.50
				2.WEIGHT	0.00	0.00	2.00	1.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.33	0.17	0.33
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	1.25	1.25	1.00	1.00	1.00	0.75	0.00
				6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.67	1.33	1.33	0.33
				7.Total score	6.08	6.08	7.17	6.00	4.50	4.33	4.08
535		Placebo	Male	1.ANKIETY/SOMATIZATION	2.17	2.17	2.33	2.33	2.00	1.67	1.67
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	1.00	1.00	1.00	0.67	0.50
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	1.75	1.75	1.75	2.00	1.75	1.75	1.75
				6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.67	1.33	0.00
				7.Total score	5.42	5.42	5.75	6.00	5.75	3.92	3.92
536		Reboxetine	Female	1.ANKIETY/SOMATIZATION	1.67	1.67	1.67	1.33	1.33	1.33	1.33
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.33	0.17	0.17	0.17
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	2.00	1.75	1.50	1.25	1.25
				6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.33	0.00	0.00	0.00
				7.Total score	4.83	4.83	3.92	3.50	3.00	2.75	2.75
7/03	187	Imipramine	Female	1.ANKIETY/SOMATIZATION	1.17	1.17	1.17	1.17	1.17	0.33	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.50	0.33	0.17
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	0.00
				5.RETARDATION	1.75	1.75	1.75	1.75	1.75	1.75	0.50
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.33	1.33	0.67
				7.Total score	6.75	6.75	6.75	6.75	6.75	3.08	1.17

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	188	Placebo	Male	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	0.50	0.67	0.67	0.67
				2.WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.50	0.50	
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	
				5.RETARDATION	1.75	1.75	1.75	1.00	1.50	1.50	
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.33	0.33	
				7.Total score	5.92	5.92	5.92	3.17	3.00	3.00	
					1.17	1.17	1.17	0.83	0.50	0.33	
189	Placebo	Male	1.ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			2.WEIGHT	0.50	0.67	0.67	0.17	0.17	0.33		
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.00	0.00	0.00		
			4.DIURNAL VARIATION	2.25	2.25	2.25	1.00	0.50	0.75		
			5.RETARDATION	1.67	1.67	1.67	0.00	0.00	0.33		
			6.SLEEP DISTURBANCE	6.58	6.58	6.75	3.67	1.17	1.75		
			7.Total score	0.83	0.83	0.83	0.50	0.50	0.50		
				0.00	1.00	0.00	0.00	0.00	0.00		
190	Reboxetine	Male	1.ANXIETY/SOMATIZATION	0.00	0.50	0.67	0.50	0.33	0.33		
			2.WEIGHT	0.50	0.50	0.67	0.50	0.33	0.33		
			3.COGNITIVE DISTURBANCE	2.00	2.00	1.00	1.00	0.00	0.00		
			4.DIURNAL VARIATION	1.75	1.75	2.00	2.00	1.00	1.25		
			5.RETARDATION	1.67	1.67	1.00	1.00	0.67	0.33		
			6.SLEEP DISTURBANCE	6.75	7.75	5.50	5.50	2.67	2.42		
			7.Total score	1.33	1.33	0.67	0.67	0.50	0.83		
				1.00	1.00	0.00	0.00	0.00	0.00		
191	Imipranino	Female	1.ANXIETY/SOMATIZATION	0.83	1.00	0.33	0.33	0.33	0.33		
			2.WEIGHT	1.00	1.00	1.00	1.00	1.00	1.00		
			3.COGNITIVE DISTURBANCE	0.83	1.00	0.33	0.33	0.33	0.33		
			4.DIURNAL VARIATION	2.00	2.50	1.50	1.50	1.00	1.25		
			5.RETARDATION	1.33	1.67	1.00	1.00	0.33	0.67		
			6.SLEEP DISTURBANCE	7.50	8.50	4.50	4.50	2.17	4.08		
			7.Total score	1.00	1.00	1.00	0.83	0.83	0.50		
				0.63	0.83	0.83	0.33	0.33	0.33		
192	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.00		
			2.WEIGHT	0.83	0.83	0.83	0.33	0.33	0.33		
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00		
			4.DIURNAL VARIATION	1.75	1.75	1.00	1.00	1.00	1.00		
			5.RETARDATION	1.00	1.00	0.67	0.67	1.00	1.00		
			6.SLEEP DISTURBANCE	6.58	6.58	6.58	3.85	2.85	2.85		
			7.Total score	1.33	1.17	1.17	1.17	1.17	1.17		
				0.00	0.00	0.00	0.00	0.00	0.00		
523	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.33	1.33	0.17	0.17			
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00			
			3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00	1.25			
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00			
			5.RETARDATION	0.00	0.00	0.00	0.00	0.00			

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
7/03	523	Reboxetine	Female	6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.00	1.00	1.00	1.00			
				7.Total score	6.33	6.50	6.50	3.83	3.58	3.58	3.58			
				524	Placebo	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.33	0.83	0.67	0.67	0.67
							2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
							3.COGNITIVE DISTURBANCE	1.00	1.00	1.17	0.83	0.33	0.33	0.33
							4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00	0.00
							5.RETARDATION	2.00	2.00	2.00	1.75	1.50	0.50	0.50
6.SLEEP DISTURBANCE	1.67	1.67	1.67				1.00	0.00	0.00	0.00				
7.Total score	7.17	7.17	7.33				6.58	3.67	1.50	1.50				
525	Placebo	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.00	0.17	0.17	0.17				
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
			3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.33	0.17	0.00	0.00				
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
			5.RETARDATION	2.25	2.25	2.25	1.75	1.00	0.75	0.75				
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	0.67	0.67	0.00	0.00				
			7.Total score	6.42	6.42	6.42	4.08	3.00	1.08	0.92				
526	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	0.67	0.33				
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.50	0.17	0.17				
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
			5.RETARDATION	2.50	2.50	2.50	2.00	2.00	1.00	0.25				
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	0.00				
			7.Total score	6.17	6.17	6.17	5.50	5.50	2.83	0.75				
527	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.00	1.00	1.00	1.00				
			2.WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	0.00				
			3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.83	0.33	0.33	0.33				
			4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00	0.00				
			5.RETARDATION	2.00	2.00	2.00	2.00	1.25	1.25	1.25				
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	1.00				
			7.Total score	7.33	7.33	7.33	3.58	3.58	3.58	3.58				
528	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.00	1.00	1.00	1.00	1.17				
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
			3.COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.50	0.50	0.50	0.50				
			4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00				
			5.RETARDATION	2.00	1.75	1.50	1.50	1.50	1.75	1.75				
			6.SLEEP DISTURBANCE	1.33	1.00	0.67	0.67	0.67	1.00	1.00				
			7.Total score	6.33	5.75	3.67	3.67	3.67	3.67	4.42				
7/04	193	Placebo	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.17	0.50	0.50				
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.67	0.33	0.17				

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36

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
7/04	193	Placebo	Female	1.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00	
				4. DIURNAL VARIATION	1.75	1.75	1.75	1.75	0.50	0.50	0.00	0.00
				5. RETARDATION	2.00	2.00	2.00	1.33	0.67	0.33	0.33	
				6. SLEEP DISTURBANCE	7.08	7.08	7.08	4.58	1.83	1.00	1.00	
				7. Total score								
				1.33	1.33	1.33	0.83	0.50	0.33	0.33		
				3.00	3.00	3.00	2.00	0.00	0.00	0.00		
194	Reboxetine	Male	1.17	0.83	1.17	1.17	0.67	0.50	0.17	0.17		
			4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	1.00	1.00		
			5. RETARDATION	2.00	2.50	2.00	2.00	0.75	0.50	0.50		
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	1.00	0.67	0.33		
			7. Total score	9.50	9.67	9.50	6.08	2.75	2.67	2.33		
			1.50	1.50	1.50	0.83	0.33	0.33	0.17			
			0.00	0.00	0.00	0.00	0.00	0.00	0.00			
195	Placebo	Female	0.83	0.83	0.83	0.83	0.50	0.33	0.33	0.33		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00		
			5. RETARDATION	1.75	1.75	1.75	1.75	0.50	0.50	0.75		
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	0.67	0.33	0.33		
			7. Total score	7.08	7.08	7.08	4.42	1.83	1.83	1.58		
			1.50	1.50	1.50	1.50	1.17	1.00	0.50	0.50		
			0.00	0.00	0.00	0.00	0.00	0.00	0.00			
196	Reboxetine	Female	0.83	0.83	0.83	0.83	0.50	0.33	0.17	0.17		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00		
			5. RETARDATION	1.75	1.75	1.75	1.25	0.75	0.50	0.50		
			6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.33	0.00	0.00		
			7. Total score	6.42	6.42	6.42	4.32	3.08	1.50	1.17		
			1.50	1.50	1.50	1.50	1.17	1.00	0.50	0.50		
			0.00	0.00	0.00	0.00	0.00	0.00	0.00			
197	Imipramine	Male	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.83		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	1.75	1.75	1.75	1.75	1.75	1.75	1.75		
			6. SLEEP DISTURBANCE	1.33	1.33	2.00	2.00	2.00	2.00	1.67		
			7. Total score	7.42	7.42	7.08	7.08	7.08	7.08	6.75		
			1.50	1.50	1.50	1.50	1.50	1.50	1.50			
			0.00	0.00	0.00	0.00	0.00	0.00	0.00			
198	Imipramine	Female	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.83		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	1.75	1.75	1.75	1.75	1.75	1.75	1.75		
			6. SLEEP DISTURBANCE	1.33	1.33	2.00	2.00	2.00	2.00	1.67		
			7. Total score	7.42	7.42	7.08	7.08	7.08	7.08	6.75		
			1.50	1.50	1.50	1.50	1.50	1.50	1.50			
			0.00	0.00	0.00	0.00	0.00	0.00	0.00			
199	Imipramine	Male	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.83		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	1.75	1.75	1.75	1.75	1.75	1.75	1.75		
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	1.67		
			7. Total score	6.92	6.92	6.92	6.92	6.92	6.92	6.75		
			1.50	1.50	1.50	1.50	1.50	1.50	1.50			
			0.00	0.00	0.00	0.00	0.00	0.00	0.00			

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PHARMACIA CNS RD

REBOXETINE - PROTOCOL 20124/015

Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
7/04	199	Imipramine	Male	2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.83	0.50	0.33	0.17	
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
				5.RETARDATION	2.00	2.00	2.00	1.75	1.25	1.00	1.00	
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.33	1.00	1.00	
				7.Total score	8.00	8.00	8.00	7.00	6.75	5.08	4.33	4.17
				1.ANKIETY/SOMATIZATION	1.33	1.33	1.33	1.17	1.17	1.17	1.00	1.00
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
200	Placebo	Male	1.ANKIETY/SOMATIZATION	1.00	1.00	1.00	1.00	0.83	0.67	0.67		
			2.WEIGHT	1.00	1.00	1.00	1.00	0.83	0.67	0.67		
			3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00		
			4.DIURNAL VARIATION	1.75	1.75	1.75	1.50	1.25	1.25	1.25		
			5.RETARDATION	1.67	1.67	1.67	1.67	1.33	1.17	1.17		
			6.SLEEP DISTURBANCE	7.75	7.75	7.75	7.58	7.17	6.58	6.58		
			7.Total score	1.33	1.33	1.33	1.50	1.00	1.00	0.67	0.67	
			1.ANKIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
201	Reboxetine	Female	1.ANKIETY/SOMATIZATION	0.67	0.67	0.67	0.67	0.50	0.50	0.33		
			2.WEIGHT	2.00	2.00	2.00	2.00	2.00	2.00	2.00		
			3.COGNITIVE DISTURBANCE	2.25	2.25	2.25	2.25	1.50	1.50	1.25		
			4.DIURNAL VARIATION	1.67	1.67	1.67	1.67	1.33	1.00	1.00		
			5.RETARDATION	7.92	7.92	7.92	8.08	6.67	5.67	4.75		
			6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.33	1.00	0.67		
			7.Total score	1.00	1.00	1.00	1.00	0.83	0.50	0.50		
			1.ANKIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
202	Reboxetine	Male	1.ANKIETY/SOMATIZATION	0.83	0.83	0.83	0.83	0.50	0.50	0.33		
			2.WEIGHT	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			3.COGNITIVE DISTURBANCE	2.50	2.50	2.50	2.00	2.00	2.00	1.50		
			4.DIURNAL VARIATION	1.33	1.33	1.33	1.33	1.33	1.00	0.67		
			5.RETARDATION	8.00	8.00	8.00	8.00	6.33	6.33	5.00		
			6.SLEEP DISTURBANCE	1.17	1.17	1.17	1.17	1.00	1.00	0.83		
			7.Total score	1.00	1.00	1.00	1.00	0.83	0.67	0.67		
			1.ANKIETY/SOMATIZATION	0.67	0.67	0.67	0.67	0.67	0.67	0.67		
203	Placebo	Female	1.ANKIETY/SOMATIZATION	1.00	1.00	1.00	1.00	0.83	0.67	0.67		
			2.WEIGHT	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00		
			4.DIURNAL VARIATION	1.50	1.50	1.50	1.50	1.50	1.50	1.50		
			5.RETARDATION	1.67	1.67	1.67	1.67	1.33	1.33	1.33		
			6.SLEEP DISTURBANCE	7.83	7.83	8.83	8.67	7.75	5.58	5.17		
			7.Total score	1.33	1.33	1.33	1.33	1.17	1.17	1.17		
			1.ANKIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
204	Imipramine	Female	1.ANKIETY/SOMATIZATION	0.67	0.67	0.67	0.67	0.50	0.50	0.33		
			2.WEIGHT	2.00	2.00	2.00	2.00	2.00	2.00	2.00		
			3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00		
			4.DIURNAL VARIATION	1.50	1.50	1.50	1.50	1.50	1.50	1.50		
			5.RETARDATION	1.67	1.67	1.67	1.67	1.67	1.67	1.67		
			6.SLEEP DISTURBANCE	8.17	8.17	8.17	8.17	7.00	6.00	5.00		
			7.Total score	1.33	1.33	1.33	1.33	1.17	1.17	1.17		
			1.ANKIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00		

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38

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/05	205	Placebo	Male	1. ANXIETY/SOMATIZATION	1.50	1.67	1.67	1.67	1.50	1.67	1.50
				2. WEIGHT	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.83	0.83	0.83	0.83
				4. DIURNAL VARIATION	1.00	1.00	2.00	2.00	2.00	2.00	2.00
				5. RETARDATION	2.00	2.50	2.50	2.50	2.50	2.50	2.50
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				7. Total score	8.33	9.00	10.00	10.00	10.00	10.00	9.83
206		Imipramine	Female	1. ANXIETY/SOMATIZATION	1.67	1.33	1.00	1.00	1.00	1.00	1.00
				2. WEIGHT	3.00	3.00	2.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.50	0.50	0.50
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00
				5. RETARDATION	2.00	2.00	2.00	2.00	1.25	1.00	1.00
				6. SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	0.67	0.67	0.67
				7. Total score	9.67	9.67	8.00	5.50	3.42	3.42	3.17
207		Imipramine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.00	0.83	0.83	0.83
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.33	0.33	0.33	0.33
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	1.00
				5. RETARDATION	1.75	1.75	1.75	1.25	1.00	1.00	1.00
				6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.00	1.00	1.00	1.00
				7. Total score	7.42	7.42	6.08	5.25	3.17	3.17	4.17
208		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.50	1.67	1.33	1.17	0.67	0.50	0.17
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.33	0.33	0.17
				4. DIURNAL VARIATION	2.00	2.00	2.00	1.00	0.00	0.00	1.00
				5. RETARDATION	1.75	1.75	1.50	1.25	1.00	0.75	0.75
				6. SLEEP DISTURBANCE	2.00	2.00	1.00	1.00	1.00	1.00	1.00
				7. Total score	7.92	8.08	6.50	4.92	3.00	2.58	3.08
209		Placebo	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.33	1.33	1.33	1.50	1.67
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	1.00	1.00	1.00	1.00	1.00
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				5. RETARDATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.67	1.67	1.67	1.67
				7. Total score	7.33	7.33	7.67	8.00	8.17	8.33	8.33
210		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.50	1.50	1.17	0.83	0.67	0.33	0.33
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.33	0.17	0.17	0.17
				4. DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00	1.00
				5. RETARDATION	1.75	1.75	1.50	0.75	0.75	0.75	0.75

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE		Screening Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42										
Centre	Patient	Treatment	Sex	Hamilton depression rating scale	0	7	14	21	28	35	42	
7/05	210	Reboxetine	Male	6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	0.67	0.67	0.67	
				7. Total score	6.75	6.75	5.17	2.75	2.42	1.92	2.92	1.92
				1. ANXIETY/SOMATIZATION	1.50	1.67	1.33	1.00	0.67	0.17	0.17	0.17
541	Reboxetine	Female	2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.33	0.33	0.33		
			4. DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	1.00	1.00	0.00	
542	Imipramine	Male	5. RETARDATION	2.25	2.25	1.50	0.75	0.75	0.75	0.75	0.75	
			6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.00	0.33	0.00	0.00	0.00	
			7. Total score	8.08	8.25	6.83	3.25	2.08	2.25	2.25	1.25	
543	Imipramine	Male	1. ANXIETY/SOMATIZATION	2.17	2.17	2.00	1.83	1.50	1.17	1.17	1.17	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	0.67	0.67	0.67	0.67	
544	Placebo	Female	4. DIURNAL VARIATION	2.00	2.00	2.00	1.80	1.80	2.00	2.00	2.00	
			5. RETARDATION	2.75	2.75	2.50	2.00	2.00	2.00	1.75	1.75	
			6. SLEEP DISTURBANCE	2.00	2.00	1.67	1.00	1.00	1.00	1.00	1.00	
545	Placebo	Male	7. Total score	9.92	8.92	9.17	6.83	5.17	6.83	6.58	4.58	
			1. ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.67	0.50	0.50	0.50	0.50	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
546	Reboxetine	Female	3. COGNITIVE DISTURBANCE	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	
			4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	2.00	2.00	2.00	2.00	
			5. RETARDATION	2.25	2.25	2.25	2.25	2.25	2.25	2.25	2.25	

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40

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
7/05	546	Reboxetine	Female	4. DIURNAL VARIATION	0.00	1.00	1.00	1.00	0.00	1.00	0.00	
				5. RETARDATION	2.25	2.00	1.50	1.00	0.75	0.75		
				6. SLEEP DISTURBANCE	1.33	1.33	1.00	1.00	1.00	1.00		
				7. Total score	5.75	6.75	6.00	5.00	4.17	2.75	3.75	2.75
				1. ANXIETY/SOMATIZATION	1.50	1.17	1.50	1.00	0.83	0.83		
				2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.50	0.50	0.50		
7/07	529	Placebo	Female	4. DIURNAL VARIATION	1.00	1.00	2.00	2.00	1.00	1.00		
				5. RETARDATION	2.00	1.75	1.25	1.00	1.25	1.25		
				6. SLEEP DISTURBANCE	2.00	1.67	2.00	2.00	2.00	2.00		
				7. Total score	7.17	6.25	7.75	6.75	6.33	5.58	5.58	
				1. ANXIETY/SOMATIZATION	1.17	1.17	1.33	1.50				
				2. HEIGHT	0.00	0.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.67				
530		Imipramine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
				5. RETARDATION	2.00	2.00	1.75	1.75				
				6. SLEEP DISTURBANCE	1.67	2.00	2.00	2.00				
				7. Total score	6.67	7.00	6.58	6.92				
				1. ANXIETY/SOMATIZATION	1.17	1.17	1.33	1.50				
				2. HEIGHT	0.00	0.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.67				
531		Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
				5. RETARDATION	1.50	1.50	1.75	1.25	1.50	2.00		
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	1.67	2.00		
				7. Total score	6.67	6.50	7.08	4.75	4.67	5.67	5.42	
				1. ANXIETY/SOMATIZATION	1.17	1.00	1.17	1.00	1.00	1.33	0.83	
				2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
				3. COGNITIVE DISTURBANCE	1.00	1.00	1.17	0.83	0.50	0.67	0.50	
532		Imipramine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
				5. RETARDATION	1.75	2.25	2.00	1.75	1.75	1.75		
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	2.00	1.33		
				7. Total score	6.75	7.58	7.17	6.42	6.75	5.75	4.92	
				1. ANXIETY/SOMATIZATION	1.33	1.67	1.67	1.50	1.33	1.33	1.17	
				2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.83	0.67	0.33	0.17	
533		Reboxetine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
				5. RETARDATION	1.75	2.25	2.00	1.75	1.75	1.75		
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	2.00	1.33		
				7. Total score	6.75	7.58	7.17	6.42	6.75	5.75	4.92	
				1. ANXIETY/SOMATIZATION	1.17	1.67	1.33	1.50	1.33	1.33	1.33	
				2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
				3. COGNITIVE DISTURBANCE	0.83	1.00	0.83	0.83	0.50	0.50	0.50	
534		Placebo	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
				5. RETARDATION	2.00	2.00	2.00	2.00	2.00	2.00		
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00		
				7. Total score	6.50	6.67	7.17	7.33	7.17	5.83	4.92	
				1. ANXIETY/SOMATIZATION	1.83	1.50	1.50	1.50	1.33	1.50	1.17	
				2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
				3. COGNITIVE DISTURBANCE	0.83	1.00	0.83	0.83	0.50	0.50	0.50	

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41

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Screen Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
7/07	534	Placebo	Female	Hamilton depression rating scale									
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.50	0.50	0.50	0.33	0.33	0.33
				4.DIURNAL VARIATION	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.00	1.50	1.75	1.75	1.50	1.50	1.50	1.50	1.50
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	1.67	1.67	1.67	1.67	1.00
				7.Total score	6.67	6.83	7.08	6.58	6.00	6.17	4.67	4.00	
8	211	Reboxetine	Female	Hamilton depression rating scale									
				1.ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.83					
				2.WEIGHT	0.00	0.00	0.00	0.00					
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.67					
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00					
				5.RETARDATION	2.25	2.25	2.50	2.50					
				7.Total score	1.33	1.33	1.33	1.33					
212	212	Placebo	Female	Hamilton depression rating scale									
				1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.33	1.50	1.50	1.50	1.50	1.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	2.00	2.00	1.75	1.75	2.00	2.00	2.00
				7.Total score	1.33	1.33	1.33	1.33	1.00	1.00	1.33	1.33	1.33
213	213	Imipramine	Male	Hamilton depression rating scale									
				1.ANXIETY/SOMATIZATION	1.50	1.50							
				2.WEIGHT	0.00	0.00							
				3.COGNITIVE DISTURBANCE	1.00	1.00							
				4.DIURNAL VARIATION	0.00	0.00							
				5.RETARDATION	2.00	2.00							
				7.Total score	1.33	1.33							
214	214	Reboxetine	Female	Hamilton depression rating scale									
				1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.17	1.17	1.17	1.17	1.17	1.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33	0.33
				4.DIURNAL VARIATION	0.00	0.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.50	2.50	2.25	2.25	2.25	2.25	2.00	2.00	2.00
				7.Total score	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
215	215	Placebo	Female	Hamilton depression rating scale									
				1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	0.83	0.83	0.83	0.83	0.83	0.83
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.17	0.17	0.17	0.17	0.00	0.00
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	1.75	1.75	1.00	0.75	0.50	0.50	0.50
				7.Total score	1.33	1.33	0.33	0.33	0.00	0.00	0.00	0.00	0.00

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42

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PHARMACIA CNS RD
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	216	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.00	1.00	0.83	0.83
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.33	0.33	0.33	
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	
				5. RETARDATION	2.25	2.25	2.25	2.00	2.00	1.75	
				6. SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	0.67	0.00	
				7. Total score	5.08	5.08	4.75	4.42	4.00	3.33	
217	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	1.00	0.67	0.17	0.17	0.00	0.17
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.17	0.17	0.00		
			4. DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00		
			5. RETARDATION	2.25	2.25	2.00	1.25	1.00	1.00		
			6. SLEEP DISTURBANCE	1.00	1.00	0.33	0.33	0.00	0.00		
			7. Total score	5.75	5.75	4.67	3.08	1.92	1.33		
218	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.33	1.17	1.17	0.83	0.50	0.33	0.33
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.50	0.50	0.50		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	2.00	2.00	2.00	2.00	2.00	1.50		
			6. SLEEP DISTURBANCE	1.00	1.00	1.00	0.67	0.67	0.33		
			7. Total score	5.83	6.00	5.67	5.33	5.00	3.83		
219	Placebo	Female	1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.67	0.50			
			2. WEIGHT	1.00	1.00	1.00	0.00	0.00			
			3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.33	0.17			
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00			
			5. RETARDATION	2.00	2.00	2.00	1.75	1.50			
			6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.33	0.33			
			7. Total score	6.50	6.50	5.17	4.08	2.50			
220	Imipramine	Female	1. ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.67
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.33	0.17	0.17		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00		
			5. RETARDATION	2.25	2.25	2.25	1.75	1.50	1.00		
			6. SLEEP DISTURBANCE	1.00	1.00	1.00	0.33	0.33	0.33		
			7. Total score	5.75	5.75	5.42	5.25	2.83	2.17		
221	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.83	0.50	0.33	0.17	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.67	0.50	0.33	0.17	0.17	0.00		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00		
			5. RETARDATION	2.25	2.25	2.25	1.75	1.50	1.00		

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43

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	221	Imipramine	Male	6. SLEEP DISTURBANCE	0.67	1.00	0.67	0.33	0.33	0.33	0.33
				7. Total score	5.58	5.75	5.08	2.75	2.50	1.83	1.25
222	Placebo	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	0.67	0.33	0.33	0.33	0.33	0.33
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.33	0.33	0.17	0.00	0.00	0.00	0.00	0.00
			4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	2.25	2.25	1.50	1.75	0.25	0.50	0.50	0.50
			6. SLEEP DISTURBANCE	1.00	1.00	0.33	0.00	0.00	0.00	0.00	0.00
			7. Total score	5.75	5.75	2.83	2.00	1.08	0.58	1.50	1.50
223	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.17	1.33	1.33	1.00	0.67	0.67	0.67	0.50
			2. WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.67	0.50	0.67	0.33	0.17	0.17	0.00	0.00
			4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	2.25	2.25	2.25	2.00	1.75	1.50	1.25	1.25
			6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	0.33	0.33	0.33	0.33
			7. Total score	6.08	6.08	4.25	4.00	3.25	2.67	2.08	2.08
224	Placebo	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	0.83	0.67	0.67	0.67	0.50
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.67	0.50	0.33	0.33	0.17	0.17	0.17	0.17
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
			5. RETARDATION	2.00	2.00	2.00	1.75	1.75	1.75	1.25	1.00
			6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	0.67	0.67	0.33	0.33
			7. Total score	6.00	5.83	5.17	4.58	4.42	4.25	3.42	3.00
225	Placebo	Male	1. ANXIETY/SOMATIZATION	1.17	1.33	1.33	1.33	1.33	1.17	0.67	0.50
			2. WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.50	0.33	0.33	0.33
			4. DIURNAL VARIATION	0.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00
			5. RETARDATION	1.75	1.75	1.75	1.75	1.75	1.50	1.50	1.25
			6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.33	1.33	1.00	0.67	0.33
			7. Total score	6.08	6.25	7.25	5.92	5.92	5.25	4.17	3.42
226	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.17	1.17	1.17	1.17	1.17
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.50	0.50	0.50	0.50
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
			5. RETARDATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
			6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.33	1.00	1.00	1.00
			7. Total score	6.33	6.33	6.00	6.00	6.00	5.67	5.67	5.67
227	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.33	1.17	1.00	1.00	0.83
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.50	0.50	0.33	0.33

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44

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	227	Reboxetine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.00	2.00	1.75	1.75	1.75	1.75	
				6. SLEEP DISTURBANCE	1.00	1.33	1.00	1.00	0.67	0.67	
				7. Total score	6.00	6.33	5.83	5.58	5.42	4.92	
				1. ANXIETY/SOMATIZATION	1.17	1.33	1.33				
				2. WEIGHT	1.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.67				
	228	Imipramine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	1.75	2.00	2.00				
				6. SLEEP DISTURBANCE	1.00	1.33	1.33				
				7. Total score	6.42	6.17	6.33				
				1. ANXIETY/SOMATIZATION	1.33	1.33	1.33				
				2. WEIGHT	0.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67				
	229	Imipramine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.00	2.00	2.00	2.00	1.75	1.75	
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.00	1.00	
				7. Total score	6.33	6.33	5.50	5.25	4.92	4.92	
				1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	0.83	0.83	0.83	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.33	0.33	0.33	
	230	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.25	2.25	2.25	2.00	2.00	1.75	
				6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.33	1.00	1.00	
				7. Total score	7.58	6.75	6.56	6.25	5.83	5.08	
				1. ANXIETY/SOMATIZATION	1.17	1.33	1.17	1.17	1.00	1.00	
				2. WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.33	0.33	
	231	Imipramine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.25	2.25	2.25	2.00	2.00	1.75	
				6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.33	1.00	1.00	
				7. Total score	7.58	6.75	6.56	6.25	5.83	5.08	
				1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.00	0.83	0.67	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.17	0.00	0.00	
	232	Reboxetine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.00	2.00	2.00	1.75	1.75	1.25	
				6. SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	0.67	0.33	
				7. Total score	6.00	6.00	5.83	5.08	4.42	3.75	
				1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	0.83	0.83	0.67	
				2. WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.33	0.17	
	233	Placebo	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.00	2.00	2.00	1.75	1.75	1.25	
				6. SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	0.67	0.67	
				7. Total score	7.00	7.00	6.67	5.08	4.92	4.25	
				1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.17	0.83	0.67	
				2. WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.33	0.17	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
8	233	Female	2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.33	0.33	0.17	0.00	0.00	
			4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			5.RETARDATION	2.00	2.00	2.00	2.00	1.75	1.75	1.25	1.25	1.25	
			6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.67	0.67	0.67	0.67	0.67	
			7.Total score	6.33	6.33	6.33	5.67	4.58	4.42	2.75	2.75	2.75	
			234	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.17	0.83	0.83	0.83	0.83	0.83
					2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
3.COGNITIVE DISTURBANCE	0.67	0.67			0.50	0.50	0.50	0.50	0.33	0.33			
4.DIURNAL VARIATION	1.00	1.00			1.00	1.00	1.00	1.00	1.00	1.00			
5.RETARDATION	2.00	2.00			2.00	2.00	2.00	1.75	1.75	1.75			
6.SLEEP DISTURBANCE	1.00	1.00			1.00	1.00	1.00	0.67	0.67	0.67			
7.Total score	6.00	6.00			5.83	5.67	5.33	4.75	4.58	4.58			
8/A	235	Female			1.ANXIETY/SOMATIZATION	1.67	1.63	1.50	1.33	1.00	0.67	1.00	1.00
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3.COGNITIVE DISTURBANCE	1.17	1.17	0.67	0.50	0.33	0.33	0.33	0.17		
			4.DIURNAL VARIATION	1.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00		
			5.RETARDATION	2.00	2.00	1.50	1.50	1.50	1.50	1.50	1.25		
			6.SLEEP DISTURBANCE	1.33	1.67	1.33	1.00	1.33	0.67	1.00	1.00		
			7.Total score	7.17	8.67	6.33	5.67	4.83	4.83	4.50	4.42		
			236	Female	1.ANXIETY/SOMATIZATION	1.83	1.83	1.33	0.67	0.50	0.67	0.33	0.50
2.WEIGHT	2.00	1.00			1.00	0.00	0.00	0.00	0.00	0.00			
3.COGNITIVE DISTURBANCE	1.00	1.00			0.50	0.33	0.17	0.00	0.00	0.00			
4.DIURNAL VARIATION	0.00	0.00			0.00	0.00	0.00	0.00	0.00	0.00			
5.RETARDATION	2.00	2.00			1.75	1.50	1.25	1.00	1.00	0.75			
6.SLEEP DISTURBANCE	1.00	1.33			1.67	1.33	1.00	0.67	1.00	0.67			
7.Total score	7.83	7.17			6.25	3.83	3.08	2.50	2.33	1.92			
237	Reboxetine	1.ANXIETY/SOMATIZATION			1.67	2.00	1.67	1.00	0.67	0.83	0.50	0.33	
		2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
		3.COGNITIVE DISTURBANCE	1.50	1.33	0.83	0.50	0.33	0.00	0.17	0.17			
		4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	0.00	0.00			
		5.RETARDATION	1.75	2.00	1.50	1.00	1.00	1.00	0.75	0.75			
		6.SLEEP DISTURBANCE	1.33	1.67	1.33	1.00	1.33	1.00	0.67	0.67			
		7.Total score	8.25	9.00	6.33	5.33	3.00	3.17	2.42	1.92			
		238	Reboxetine	1.ANXIETY/SOMATIZATION	1.00	1.33	1.00	1.00	0.83	0.67	0.67	0.83	
2.WEIGHT	1.00			1.00	1.00	0.00	0.00	0.00	0.00	0.00			
3.COGNITIVE DISTURBANCE	1.00			1.00	0.50	0.17	0.00	0.00	0.00	0.00			
4.DIURNAL VARIATION	1.00			1.00	1.00	1.00	0.00	0.00	0.00	0.00			
5.RETARDATION	2.25			2.25	1.75	1.25	1.25	1.00	1.00	1.00			
6.SLEEP DISTURBANCE	1.33			1.33	1.67	1.80	1.00	0.67	0.67	0.33			
7.Total score	7.58			7.92	6.92	4.42	3.08	2.33	2.58	2.17			

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46

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PIARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 12.1

Centre	Patient	Treatment	Sex	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE									
				Hamilton depression rating scale									
				Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
8/A	239	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.17	1.33	1.17	1.33	1.00	0.83	0.50	0.50	
				2. HEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	0.83	0.67	0.33	0.33	0.17	0.00	0.00	0.00
				4. DIURNAL VARIATION	1.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.25	2.25	1.50	1.50	1.25	1.00	1.25	1.00	1.25
				6. SLEEP DISTURBANCE	1.33	1.67	1.00	0.67	0.67	0.67	0.67	0.67	0.67
				7. Total score	7.75	9.08	5.33	3.83	3.50	2.92	2.17	2.42	
240	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	0.83	0.83	0.83	0.83	0.83		
			2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.67	0.50	0.33	0.33	0.33		
			4. DIURNAL VARIATION	1.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	2.25	2.25	1.75	1.75	1.50	1.50	1.50	1.25		
			6. SLEEP DISTURBANCE	1.00	1.33	1.67	1.33	1.33	0.67	1.00	0.67		
			7. Total score	6.58	7.92	7.42	5.58	5.17	4.33	3.67	3.08		
12/206	553	Placebo	Female	1. ANXIETY/SOMATIZATION	1.00	1.17	1.00	1.00	1.00	1.00	1.00		
				2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.00	0.83	0.83	0.83	0.50	0.33	
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.90	0.90	0.90	0.90	
				5. RETARDATION	2.75	2.50	2.25	1.75	1.75	1.75	1.75	1.25	
				6. SLEEP DISTURBANCE	1.33	1.33	1.67	1.33	1.00	1.00	1.33	1.33	
				7. Total score	7.25	7.17	6.92	5.92	4.58	4.08	4.58	3.92	
554	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.00	1.00	0.83	0.83	0.67	0.67	0.67	0.50		
			2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.00	0.83	0.83	0.67	0.33	0.17	0.17	0.17		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00		
			5. RETARDATION	2.25	2.25	1.75	1.25	1.50	1.25	0.75	0.75		
			6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.00	0.67	0.67	0.67	0.67		
			7. Total score	6.92	6.75	5.75	3.75	3.17	2.75	2.25	2.08		
555	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.33	1.50	1.17	0.83	0.83	0.83	0.83	0.83		
			2. HEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.00	0.83	0.67	0.50	0.67	0.33	0.33	0.17		
			4. DIURNAL VARIATION	1.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	2.25	2.00	1.75	1.75	1.50	1.50	1.50	1.00		
			6. SLEEP DISTURBANCE	1.33	1.67	1.33	1.00	0.67	0.67	0.67	0.67		
			7. Total score	7.92	8.00	5.92	5.08	4.67	4.58	4.33	3.67		
556	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.00	0.83	0.83	0.83	0.67		
			2. HEIGHT	2.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.33	0.17	0.17	0.17	0.00		
			4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	1.00	0.00		
			5. RETARDATION	2.50	2.25	1.75	1.50	1.25	0.75	1.00	0.75		

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47

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

Centre	Patient	Treatment	Sex	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE							
				Hamilton depression rating scale							
				Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
8/A	556	Imipramine	Male	1.67	1.33	1.00	0.67	1.00	0.67	0.67	0.67
				10.17	8.58	6.58	5.50	5.25	3.42	2.67	
				7.Total score							
9	241	Placebo	Female	1.17	1.00	1.33	1.67				
				2.00	1.00	1.00	1.00				
				0.83	0.50	0.83	0.83				
				0.00	0.00	0.00	0.00				
				2.25	2.75	2.75	2.50				
				2.00	1.00	1.00	2.00				
				8.25	6.25	6.92	8.00				
				7.Total score							
242		Reboxetine	Female	1.33	1.33	0.83	1.50	1.50			
				2.00	0.00	0.00	0.00	0.00			
				0.83	0.83	0.33	0.83	0.83			
				1.00	0.00	1.00	0.00	1.00			
				2.25	2.25	1.25	2.00	2.00			
				2.00	2.00	1.33	1.00	2.00			
				9.42	6.42	4.75	5.33	7.33			
				7.Total score							
243		Reboxetine	Female	1.00	1.00	1.17	1.83				
				1.00	0.00	0.00	0.00				
				0.50	0.50	0.83	1.00				
				0.00	0.00	0.00	0.00				
				2.25	2.25	2.25	2.50				
				1.00	1.00	1.67	2.00				
				5.75	5.75	5.92	7.33				
				7.Total score							
244		Imipramine	Female	0.67	0.83	0.33	0.33	0.33			
				1.00	0.00	0.00	0.00	0.00			
				0.67	0.67	0.17	0.17	0.17			
				1.00	1.00	1.00	1.00	1.00			
				1.75	1.75	1.25	1.25	1.25			
				2.00	2.00	1.67	1.00	1.00			
				7.08	6.25	4.42	3.75	3.75			
				7.Total score							
245		Imipramine	Female	1.00	1.00	0.83	0.67	0.33	0.17	0.33	0.33
				0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				0.83	0.83	0.67	0.17	0.00	0.00	0.00	0.00
				0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				2.25	2.00	1.25	1.25	0.00	0.25	0.00	0.00
				1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.08	6.08	4.50	3.08	1.58	1.17	1.58	1.33
				7.Total score							
246		Placebo	Female	1.33	1.33	1.83	1.83	1.83	1.83	1.83	1.83
				2.00	0.00	2.00	2.00	0.00	0.00	0.00	0.00
				1.00	1.00	0.67	0.67	0.67	0.67	0.67	0.67
				3.COGNITIVE DISTURBANCE							

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48

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

Centre	Patient	Treatment	Sex	HAMILTON depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	246	Placebo	Female	4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.75	2.75	3.25	3.25	3.25	3.25	
				7. Total score	2.00	2.00	0.67	0.67	0.67	0.67	
247	Placebo	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.00	1.17	1.00		
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.50	0.67	0.67		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	2.25	2.25	2.00	1.50	1.75	1.75		
			6. SLEEP DISTURBANCE	1.00	1.00	1.33	1.33	1.67	1.67		
			7. Total score	6.25	6.25	6.00	5.33	6.25	6.08		
248	Placebo	Male	1. ANXIETY/SOMATIZATION	0.83	0.83	1.00	2.17				
			2. WEIGHT	0.00	0.00	0.00	0.00				
			3. COGNITIVE DISTURBANCE	0.50	0.67	0.83	1.33				
			4. DIURNAL VARIATION	1.00	1.00	1.00	0.00				
			5. RETARDATION	2.50	2.50	2.50	2.25				
			6. SLEEP DISTURBANCE	1.00	1.00	1.33	2.00				
			7. Total score	5.83	6.00	6.67	7.75				
249	Reboxetine	Female	1. ANXIETY/SOMATIZATION	0.83	0.67						
			2. WEIGHT	3.00	3.00						
			3. COGNITIVE DISTURBANCE	0.67	0.83						
			4. DIURNAL VARIATION	0.00	0.00						
			5. RETARDATION	2.50	2.50						
			6. SLEEP DISTURBANCE	1.67	1.00						
			7. Total score	8.67	8.00						
250	Imipramine	Female	1. ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.67	0.83	0.83		
			2. WEIGHT	0.00	2.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.33	0.50	0.50		
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	2.50	2.50	2.50	2.00	2.25	2.25		
			6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.00	1.00	1.00		
			7. Total score	6.33	8.33	6.33	5.00	5.42	5.58		
251	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.00	1.00	0.83	1.33	0.17	0.17		
			2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.00	1.00	0.50	0.83	0.17	0.17		
			4. DIURNAL VARIATION	0.00	0.00	1.00	1.00	0.00	0.00		
			5. RETARDATION	3.00	3.00	1.75	2.00	0.50	0.25		
			6. SLEEP DISTURBANCE	0.33	0.33	1.00	1.00	0.33	0.33		
			7. Total score	7.33	7.33	5.08	6.17	1.17	0.92		
252	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.00	1.17	1.17	1.50	1.83			

1298

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

Centre	Patient Treatment	Sex	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE									
			Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
9	252	Reboxetine	Female	2.WEIGHT	0.00	0.00	0.00	1.00	1.00	1.00	1.00	1.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.67	0.83	1.00			
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00			
				5.RETARDATION	2.00	2.25	2.50	2.25	2.25			
				6.SLEEP DISTURBANCE	1.67	1.67	2.00	2.00	2.00			
				7.Total score	5.17	5.58	6.33	7.58	8.08			
				1.ANXIETY/SOMATIZATION	1.00	1.00	1.67					
				2.WEIGHT	0.00	0.00	0.00					
	253	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.50	0.50	0.83					
				2.WEIGHT	0.00	0.00	1.00					
				3.COGNITIVE DISTURBANCE	0.00	0.00	1.00					
				4.DIURNAL VARIATION	2.75	2.75	2.00					
				5.RETARDATION	2.00	2.00	2.00					
				6.SLEEP DISTURBANCE	6.25	6.25	7.50					
				7.Total score	1.67	1.67	2.00	2.00				
				1.ANXIETY/SOMATIZATION	2.00	0.00	0.00					
	254	Imipramine	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
				2.WEIGHT	0.83	0.83	1.00	1.00				
				3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00				
				4.DIURNAL VARIATION	2.25	2.25	2.50	2.50				
				5.RETARDATION	1.33	1.33	2.00	2.00				
				6.SLEEP DISTURBANCE	10.08	8.08	9.50	9.50				
				7.Total score	1.00	1.00	1.00	1.50	1.50	1.67		
				1.ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00		
	255	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	0.83	1.00	1.00	1.50	1.50	
				2.WEIGHT	1.00	1.00	1.00	1.00	1.00	1.00		
				3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	1.75	1.75			
				4.DIURNAL VARIATION	0.67	1.00	1.00	2.00	2.00			
				5.RETARDATION	5.50	5.83	5.83	7.25	7.25			
				6.SLEEP DISTURBANCE	1.33	1.33	1.50	0.33	0.33	1.00		
				7.Total score	2.00	1.00	0.00	0.00	0.00	0.00		
				1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.17	0.17	0.17		
	256	Imipramine	Female	1.ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00		
				4.DIURNAL VARIATION	2.75	2.75	2.75	0.50	0.50	1.00		
				5.RETARDATION	2.00	2.00	2.00	1.67	1.67	2.00		
				6.SLEEP DISTURBANCE	9.08	8.08	7.25	2.67	2.67	3.50		
				7.Total score	1.17	1.17	1.17					
				1.ANXIETY/SOMATIZATION	2.00	2.00	0.00					
	257	Placebo	Male	1.ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.67	0.67	0.67	0.67	
				2.WEIGHT	1.00	1.00	1.00	1.00	1.00	1.00		
				3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00		
				5.RETARDATION	1.00	1.00	1.00	1.00	1.00	1.00		
				6.SLEEP DISTURBANCE	7.83	7.83	7.83	5.83	5.83			
				7.Total score								
				1.ANXIETY/SOMATIZATION								

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50

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PHARMACIA CNS RD

REBOMETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	258	Placebo	Male	1. ANXIETY/SOMATIZATION	1.33	1.33	1.83	1.83			
				2. WEIGHT	1.00	1.00	0.00	0.00			
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.83	0.83			
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00			
				5. RETARDATION	2.25	2.25	2.25	2.25			
				6. SLEEP DISTURBANCE	1.00	1.00	1.33	1.33			
				7. Total score	7.25	7.25	7.25	7.25			
11	319	Placebo	Male	1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.17	1.00
				2. WEIGHT	2.00	0.00	0.00	0.00	2.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.00	1.00	1.00	0.83	0.50
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				5. RETARDATION	1.75	1.75	1.75	1.75	1.75	1.75	1.50
				6. SLEEP DISTURBANCE	1.67	1.67	1.00	1.33	1.67	1.67	1.00
				7. Total score	9.58	7.58	6.75	7.08	9.42	7.42	6.75
1300	320	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.67	1.50	1.67	0.83	1.33	0.83	1.33
				2. WEIGHT	0.00	2.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	1.00	0.50	1.33	0.67	0.50
				4. DIURNAL VARIATION	2.00	2.00	2.00	0.00	0.00	1.00	1.00
				5. RETARDATION	1.50	1.50	2.00	1.25	1.75	1.00	1.25
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	1.33	1.00	0.67
				7. Total score	8.00	9.83	8.67	3.92	5.75	4.50	5.08
	321	Placebo	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.50	1.00	0.67	0.50	0.33
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.50	0.33	0.17	0.17
				4. DIURNAL VARIATION	1.00	1.00	1.00	2.00	2.00	0.00	0.00
				5. RETARDATION	1.50	1.50	1.75	1.25	1.00	0.50	0.25
				6. SLEEP DISTURBANCE	1.00	1.33	0.67	0.00	0.67	0.33	0.00
				7. Total score	5.50	5.83	5.58	4.75	4.67	1.50	0.75
	322	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.67	1.67	1.50	0.67	0.83	0.83	1.00
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	1.00	0.50	0.50	0.50	0.50	0.67
				4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	2.00	2.00
				5. RETARDATION	1.50	1.50	1.50	1.50	1.50	1.50	1.50
				6. SLEEP DISTURBANCE	0.67	1.33	1.67	1.67	1.67	1.67	1.00
				7. Total score	6.67	7.50	6.17	5.33	5.50	7.00	6.17
	323	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.33	0.17	0.17	0.50
				2. WEIGHT	2.00	2.00	2.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.33	0.17	0.17	0.17	0.00
				4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	0.00	0.00
				5. RETARDATION	1.25	1.25	0.75	1.00	1.00	0.75	0.50

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51

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	323	Male	6.SLEEP DISTURBANCE	2.00	2.00	1.00	0.67	0.33	0.00	0.00
			7.Total score	8.92	8.92	6.08	3.17	2.67	1.08	1.00
324	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.50	1.00	1.00	1.33	1.33
			2.WEIGHT	2.00	1.00	2.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.33	0.67	0.67
			4.DIURNAL VARIATION	1.00	1.00	2.00	2.00	2.00	2.00	2.00
			5.RETARDATION	1.25	1.50	1.50	1.50	1.50	1.50	1.50
			6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.67	1.33	1.33	1.33
			7.Total score	7.92	7.17	9.17	6.67	6.17	6.83	6.83
325	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.50	0.83	0.50	0.17	0.33	
			2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.17	0.00	0.00	0.00	
			4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	
			5.RETARDATION	1.25	1.25	1.00	0.50	0.25	0.25	
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.50	0.33	0.33	
			7.Total score	8.08	6.25	4.00	2.33	0.75	0.58	
326	Placebo	Male	1.ANXIETY/SOMATIZATION	1.00	1.00	1.33	1.00	1.00	0.50	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.67	0.50	0.33	0.67	0.33	0.50	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	1.75	1.75	1.75	2.00	1.75	2.75	
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	
			7.Total score	5.42	5.25	5.42	5.67	5.08	6.75	
327	Imipramine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	0.33				
			2.WEIGHT	0.00	0.00	0.00				
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.00				
			4.DIURNAL VARIATION	2.00	2.00	0.00				
			5.RETARDATION	1.50	1.50	1.50				
			6.SLEEP DISTURBANCE	2.00	2.00	0.33				
			7.Total score	7.00	7.00	2.17				
328	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.83	1.33	1.17				
			2.WEIGHT	0.00	0.00	0.00				
			3.COGNITIVE DISTURBANCE	1.33	1.17	0.83				
			4.DIURNAL VARIATION	2.00	2.00	2.00				
			5.RETARDATION	2.00	1.50	1.25				
			6.SLEEP DISTURBANCE	1.67	1.33	1.00				
			7.Total score	8.83	7.33	6.25				
329	Placebo	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.17	1.17	0.83	0.67	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.33	0.00	0.00	

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52

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

Centre	Patient	Treatment	Sex	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	329	Placebo	Female	Hamilton depression rating scale	2.00	2.00	2.00	2.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	1.50	1.25	1.25	1.25	0.50	0.00	0.25
				5. RETARDATION	1.67	2.00	2.00	1.33	0.33	0.33	0.33
				7. Total score	6.67	6.75	6.75	5.75	2.50	1.17	1.58
330		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.33	1.17	1.33	1.00	0.67	0.50	0.50
				2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.83	0.33	0.17	0.17	0.00
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	1.00
				5. RETARDATION	1.00	1.00	1.25	0.75	0.25	0.25	0.00
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	1.67	1.00	1.33
				7. Total score	8.83	8.67	7.42	5.42	4.25	2.92	2.83
331		Imipramine	Male	1. ANXIETY/SOMATIZATION	1.17	1.00	0.83	0.83	0.67	0.83	1.00
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.17	0.00	0.17	0.17
				4. DIURNAL VARIATION	1.00	1.00	1.00	0.00	1.00	2.00	2.00
				5. RETARDATION	1.25	1.25	1.00	0.75	0.50	1.00	1.00
				6. SLEEP DISTURBANCE	2.00	1.33	0.83	0.83	0.00	0.00	0.00
				7. Total score	5.92	5.08	3.50	2.75	0.83	2.83	4.00
332		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.00	1.00	0.67	0.83	0.83
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.17	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.00	1.75	1.25	0.50	0.25	0.00	0.25
				6. SLEEP DISTURBANCE	2.00	2.00	1.33	1.00	0.33	1.00	0.00
				7. Total score	7.67	7.42	4.92	2.00	1.92	0.67	1.33
333		Placebo	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.00	0.67	0.17	0.17
				2. WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.33	0.17	0.17	0.17
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	0.00	0.00
				5. RETARDATION	1.25	1.25	1.00	1.00	0.25	0.25	0.25
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				7. Total score	9.08	7.08	6.67	6.33	3.92	2.08	2.58
334		Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.50	1.50					
				2. WEIGHT	1.00	0.00					
				3. COGNITIVE DISTURBANCE	0.67	0.50					
				4. DIURNAL VARIATION	2.00	2.00					
				5. RETARDATION	1.50	1.50					
				6. SLEEP DISTURBANCE	2.00	2.00					
				7. Total score	8.67	7.50					
335		Placebo	Male	1. ANXIETY/SOMATIZATION	1.67	1.33	1.00	0.83	0.83	0.83	0.67

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PHARMACIA CNS RD
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	335	Placebo	Male	2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.33	0.33	0.33	0.33	0.33
				4.DIURNAL VARIATION	0.00	1.00	0.00	1.00	0.00	0.00	0.00
				5.RETARDATION	1.50	1.50	1.25	1.00	1.00	1.25	1.00
				6.SLEEP DISTURBANCE	0.33	0.33	0.33	1.00	1.33	1.33	1.67
				7.Total score	6.17	4.83	3.17	4.42	3.50	3.50	4.08
				1.ANXIETY/SOMATIZATION	1.50	1.50	1.50				
				2.WEIGHT	0.00	0.00	0.00				
336	Imipramine	Female	1.ANXIETY/SOMATIZATION	0.50	0.50	0.50					
			2.WEIGHT	0.00	0.00	0.00					
			3.COGNITIVE DISTURBANCE	0.00	0.00	0.00					
			4.DIURNAL VARIATION	0.00	0.00	0.00					
			5.RETARDATION	2.00	2.00	2.00					
			6.SLEEP DISTURBANCE	1.67	1.67	2.00					
			7.Total score	5.67	5.67	6.00					
			1.ANXIETY/SOMATIZATION	1.33	1.50	1.50					
337	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.00	0.00	0.00					
			2.WEIGHT	0.33	0.33	0.33					
			3.COGNITIVE DISTURBANCE	2.00	2.00	2.00					
			4.DIURNAL VARIATION	1.25	1.25	1.25					
			5.RETARDATION	2.00	1.67	1.33					
			6.SLEEP DISTURBANCE	6.92	6.75	7.08					
			7.Total score	1.17	1.17	1.33					
			1.ANXIETY/SOMATIZATION	2.00	0.00	0.00					
338	Imipramine	Male	2.WEIGHT	0.83	0.67	0.67					
			3.COGNITIVE DISTURBANCE	1.00	2.00	2.00					
			4.DIURNAL VARIATION	1.00	1.50	1.25					
			5.RETARDATION	1.67	2.00	1.33					
			6.SLEEP DISTURBANCE	7.67	7.33	6.58					
			7.Total score	1.17	0.67	0.50					
			1.ANXIETY/SOMATIZATION	2.00	0.00	0.00					
			2.WEIGHT	0.83	0.67	0.67					
12	367	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	0.67	0.50				
				2.WEIGHT	2.00	2.00	2.00				
				3.COGNITIVE DISTURBANCE	1.17	0.83	0.50				
				4.DIURNAL VARIATION	0.00	1.00	1.00				
				5.RETARDATION	2.75	2.50	1.00				
				6.SLEEP DISTURBANCE	1.67	1.67	1.00				
				7.Total score	8.75	8.67	3.75				
				1.ANXIETY/SOMATIZATION	1.00	1.17	1.17				
368	Placebo	Female	1.ANXIETY/SOMATIZATION	1.00	1.17	1.17					
			2.WEIGHT	1.00	2.00	0.00					
			3.COGNITIVE DISTURBANCE	0.50	0.17	0.17					
			4.DIURNAL VARIATION	1.00	1.00	0.00					
			5.RETARDATION	2.25	2.25	1.75					
			6.SLEEP DISTURBANCE	1.67	1.33	1.33					
			7.Total score	7.42	7.92	4.42					
			1.ANXIETY/SOMATIZATION	1.00	1.17	1.17					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42			
12	369	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.17	1.00	0.33	0.67	1.50												
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00												
				3. COGNITIVE DISTURBANCE	1.67	1.33	0.50	1.83													
				4. DIURNAL VARIATION	1.00	1.00	0.00	1.00													
				5. RETARDATION	2.00	2.00	0.25	0.75	2.25												
				6. SLEEP DISTURBANCE	1.33	1.33	0.33	0.33	1.00												
				7. Total score	7.17	6.67	1.42	2.25	7.58												
370	370	Placebo	Male	1. ANXIETY/SOMATIZATION	1.00	1.33	0.67	1.50	1.50												
				2. WEIGHT	2.00	0.00	0.00	0.00	1.00												
				3. COGNITIVE DISTURBANCE	1.17	0.67	0.33	0.83	1.50												
				4. DIURNAL VARIATION	1.00	1.00	0.00	1.00	1.00												
				5. RETARDATION	1.75	2.00	1.00	2.00	1.75												
				6. SLEEP DISTURBANCE	1.67	1.67	1.00	1.00	1.33												
				7. Total score	8.58	6.67	3.00	6.33	8.08												
371	371	Imipramine	Female	1. ANXIETY/SOMATIZATION	2.00	1.67	0.33														
				2. WEIGHT	0.00	0.00	0.00														
				3. COGNITIVE DISTURBANCE	1.17	0.50	0.50														
				4. DIURNAL VARIATION	1.00	1.00	1.00														
				5. RETARDATION	1.75	1.75	0.75														
				6. SLEEP DISTURBANCE	1.67	1.33	0.33														
				7. Total score	7.58	6.25	2.92														
372	372	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.17	1.33	1.17	0.83	0.33	0.67	0.17	1.00									
				2. WEIGHT	2.00	0.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00	1.00							
				3. COGNITIVE DISTURBANCE	1.00	1.50	1.00	0.50	0.00	0.50	0.00	0.00	0.00	0.00	0.83						
				4. DIURNAL VARIATION	2.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00						
				5. RETARDATION	2.50	2.75	1.50	1.00	0.75	0.00	0.00	0.00	0.00	0.00	1.25						
				6. SLEEP DISTURBANCE	1.67	2.00	0.67	0.33	0.33	0.00	0.33	0.00	0.33	0.00	0.67						
				7. Total score	10.33	7.58	7.33	4.67	3.42	1.17	0.50	4.75									
373	373	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.33	1.50	0.00	1.00	0.00	0.67	0.00	0.00									
				2. WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00							
				3. COGNITIVE DISTURBANCE	1.33	1.17	0.67	0.83	0.83	0.50	0.00	0.00	0.00	0.00							
				4. DIURNAL VARIATION	2.00	2.00	1.00	2.00	1.00	2.00	0.00	0.00	0.00	0.00							
				5. RETARDATION	1.75	2.00	1.00	1.25	0.50	0.75	0.25	0.00	0.00	0.00							
				6. SLEEP DISTURBANCE	1.67	1.33	0.67	1.00	0.67	1.33	1.00	0.67	1.00	1.00							
				7. Total score	10.08	8.00	3.33	6.08	3.00	6.25	3.75	1.00									
374	374	Placebo	Female	1. ANXIETY/SOMATIZATION	1.17	1.33	1.17	0.50	0.50	0.33											
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00								
				3. COGNITIVE DISTURBANCE	1.33	1.17	0.67	0.17	0.33	0.33											
				4. DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00											
				5. RETARDATION	2.25	2.25	1.50	1.00	1.75	1.00											

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PHARMACIA CNS R&D

REBORETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
12	374	Placebo	Female	6.SLEEP DISTURBANCE	0.33	0.00	0.00	0.00	1.00	1.00				
				7.Total score	6.08	5.75	4.33	1.67	2.58	2.67				
13	13	Placebo	Male	1.ANXIETY/SOMATIZATION	0.50	0.83								
				2.WEIGHT	2.00	0.00								
13	13	Placebo	Male	3.COGNITIVE DISTURBANCE	1.33	1.33	0.50	0.33	0.83	0.50	0.50	0.67		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
				5.RETARDATION	1.75	1.75	1.25	1.25	1.25	1.25	1.50	2.00	2.00	2.00
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.33	1.00	1.00	1.00	1.00	1.00
				7.Total score	6.75	6.75	4.42	4.08	4.75	4.08	4.50	5.17	5.17	5.17
				1.ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.50	0.33	0.33	0.33	0.33	0.50	0.50
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
14	14	Placebo	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	0.50	1.00	0.83	0.50	0.33	0.50		
				2.WEIGHT	1.00	1.00	0.67	1.00	1.00	0.67	0.67	0.67	0.67	
				3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
				5.RETARDATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
				6.SLEEP DISTURBANCE	0.33	0.33	0.33	0.67	0.33	0.67	0.33	0.67	0.33	
				7.Total score	7.50	7.50	4.00	7.33	6.75	4.17	4.92	3.50	3.50	
15	15	Imipramine	Female	1.ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.50	0.67	0.50	0.67	0.67		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.50	1.50	0.67	0.33	0.50	0.83	1.17	0.83	1.17	
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
				5.RETARDATION	2.25	2.25	1.50	1.00	1.00	1.00	1.75	1.75	1.75	
				6.SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	1.00	1.33	1.00	1.00	1.00	
				7.Total score	7.75	7.75	5.83	4.50	5.17	7.00	6.25	4.58	4.58	
16	16	Imipramine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	1.17	1.17	0.67	0.67	1.17			
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	0.17	0.67	0.67	0.83		
				4.DIURNAL VARIATION	1.00	1.00	2.00	2.00	0.00	2.00	2.00	2.00		
				5.RETARDATION	1.25	1.00	2.00	1.25	0.50	0.75	0.75	1.00		
				6.SLEEP DISTURBANCE	1.67	2.00	1.67	1.00	0.67	1.00	1.00	2.00		
				7.Total score	5.75	5.83	7.83	6.42	2.00	5.08	5.08	7.00		
17	17	Reborepine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	0.50	0.83	0.67	0.67	0.50			
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.50	1.50	1.00	0.50	0.50	0.17	0.17	0.17		

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	17	Reboxetine	Male	4. DIURNAL VARIATION	2.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	1.25	1.25	1.00	0.75	0.50	0.75	
				6. SLEEP DISTURBANCE	0.33	0.33	0.33	0.33	0.33	0.33	
				7. Total score	6.25	6.25	3.83	3.42	3.00	2.92	
18	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	0.33	0.33	0.33	0.67	0.33	0.33
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.33	0.33	0.33		
			4. DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00		
409	Reboxetine	Male	5. RETARDATION	2.00	2.00	1.25	0.75	1.25	1.25	1.00	0.67
			6. SLEEP DISTURBANCE	0.33	0.33	1.00	0.67	1.00	0.67		
			7. Total score	5.33	5.33	4.08	3.75	2.08	3.25		
			1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	0.83	1.00	0.83		
410	Placebo	Male	2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.83	0.50	0.50	0.50		
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00		
			5. RETARDATION	1.25	1.25	1.00	1.00	1.00	0.75		
411	Imipramine	Female	6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.33	1.67	1.33	0.67
			7. Total score	6.92	6.92	6.83	6.00	5.83	5.42		
			1. ANXIETY/SOMATIZATION	1.50	1.17	1.33	1.33	1.33	1.00		
			2. WEIGHT	0.00	0.00	1.00	1.00	1.00	0.00		
423	Placebo	Male	3. COGNITIVE DISTURBANCE	1.17	1.17	1.00	1.33	0.50	0.67	0.83	0.17
			4. DIURNAL VARIATION	0.00	0.00	2.00	2.00	2.00	0.00		
			5. RETARDATION	1.50	1.75	1.50	1.75	1.25	1.50		
			6. SLEEP DISTURBANCE	0.33	1.00	0.67	1.33	1.00	0.67		
423	Placebo	Male	7. Total score	4.50	5.08	7.50	8.75	6.58	2.92	6.17	3.58
			1. ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.67	1.17	1.67		
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.50	0.33	1.33		
44	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	1.50	1.50	1.25	1.50	1.75	1.25		
			6. SLEEP DISTURBANCE	1.33	1.33	0.67	0.00	0.00	0.33		
			7. Total score	5.83	5.83	4.75	1.67	4.50	5.00		
14	Reboxetine	Female	1. ANXIETY/SOMATIZATION	0.83	0.83	0.33	0.17	0.33	0.33	0.33	0.33
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.83	1.17	0.83		
			4. DIURNAL VARIATION	2.00	2.00	0.00	0.00	1.00	0.00		
14	Reboxetine	Female	5. RETARDATION	1.25	1.25	1.25	1.50	1.75	1.25	0.25	0.67
			6. SLEEP DISTURBANCE	1.33	1.33	0.67	1.00	1.00	0.67		
			7. Total score	6.42	6.42	2.92	3.50	5.25	1.58		
			1. ANXIETY/SOMATIZATION	1.83	1.33	1.67	0.17	1.17	1.00		

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57

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14	19	Reboxetine	Female	2.WEIGHT	0.00	1.00	2.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.50	1.50	1.17	0.33	1.00	1.00	
				4.DIURNAL VARIATION	0.00	1.00	0.00	0.00	2.00	2.00	
				5.RETARDATION	2.75	2.75	2.75	1.75	2.00	2.75	
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	2.00	2.00	
				7.Total score	8.08	9.58	9.58	3.58	8.17	8.75	
					1.17	1.17	1.00	0.67	0.17	0.17	
20	20	Imipramine	Female	1.ANKIETY/SOMATIZATION	3.00	3.00	0.00	0.00	0.00	0.00	0.00
				2.WEIGHT	0.83	0.83	0.00	0.33	0.33	0.00	
				3.COGNITIVE DISTURBANCE	1.00	1.00	2.00	1.00	1.00	1.00	
				4.DIURNAL VARIATION	1.75	1.75	1.00	0.50	0.25	0.00	
				5.RETARDATION	2.00	2.00	2.00	1.00	0.67	0.00	
				6.SLEEP DISTURBANCE	9.75	9.75	7.75	6.00	3.00	2.42	
				7.Total score	1.17	1.17	1.00	0.67	0.17	0.17	
21	21	Imipramine	Female	1.ANKIETY/SOMATIZATION	0.83	2.00	2.00	0.83	1.50	0.83	1.50
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.17	0.33	0.33	0.50	1.17	1.00	
				4.DIURNAL VARIATION	2.00	1.00	1.00	1.00	2.00	1.00	
				5.RETARDATION	2.00	1.75	1.50	1.00	1.75	1.50	
				6.SLEEP DISTURBANCE	0.67	2.00	1.33	1.00	1.00	1.00	
				7.Total score	7.67	8.08	6.17	4.93	7.42	5.33	
15	25	Reboxetine	Female	1.ANKIETY/SOMATIZATION	1.17	1.17	1.00	1.33	1.17	0.50	1.00
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	1.00	0.67	0.83	
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	
				5.RETARDATION	2.50	2.50	2.25	1.50	1.75	1.50	
				6.SLEEP DISTURBANCE	1.00	1.00	1.67	1.33	1.33	1.33	
				7.Total score	7.50	7.50	7.58	7.50	6.92	6.17	
26	26	Placebo	Male	1.ANKIETY/SOMATIZATION	1.33	1.33	1.17	0.83	0.67	0.83	0.67
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.67	0.50	0.67	
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	
				5.RETARDATION	1.75	1.75	1.00	1.25	1.50	1.00	
				6.SLEEP DISTURBANCE	1.67	1.67	1.00	1.33	1.00	1.33	
				7.Total score	6.92	6.92	5.25	4.83	3.42	5.17	
27	27	Imipramine	Female	1.ANKIETY/SOMATIZATION	1.33	1.33	0.83	1.00	0.50	0.33	0.33
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.83	0.17	0.33	
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	
				5.RETARDATION	2.00	2.00	1.50	1.50	1.00	0.75	
				6.SLEEP DISTURBANCE	1.67	1.67	0.67	0.67	0.33	0.33	
				7.Total score	6.83	6.83	4.67	5.00	3.33	1.75	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
15	28	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	0.67	0.50	0.33	0.33	0.67	0.50	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.33	0.33	0.33	0.33	0.17	0.17
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	1.75	1.75	1.50	1.00	1.00	1.00	0.75	0.25	0.25
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.33	0.33	0.67	0.67	0.67
				7. Total score	6.08	6.08	5.17	3.50	3.00	3.00	3.42	3.42	0.92
29		Placebo	Male	1. ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.67	1.33				
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.83	0.67				
				4. DIURNAL VARIATION	1.00	1.00	2.00	2.00	2.00				
				5. RETARDATION	2.25	2.25	2.25	2.00	2.25				
				6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	1.00				
				7. Total score	6.75	6.75	7.42	7.17	7.25				
30		Imipramine	Female	1. ANXIETY/SOMATIZATION	0.83	0.83	1.17	1.00	0.50	0.67	0.50	0.67	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	0.33	0.67	0.17	0.33	0.33
				4. DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.00	2.00	1.75	1.75	1.00	1.56	1.00	1.00	1.00
				6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.33	0.33	0.33	0.33	0.33	0.33
				7. Total score	6.83	6.83	6.58	5.08	2.17	4.17	2.00	2.33	2.33
403		Imipramine	Female	1. ANXIETY/SOMATIZATION	1.00	1.00	0.50	0.67	0.67	0.50	0.67	0.50	
				2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.17	0.33	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.25	2.25	1.00	1.25	1.00	0.50	0.50	0.50	0.50
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.67	0.67	0.67	0.67	0.67
				7. Total score	8.42	8.42	3.33	2.75	2.67	1.67	1.83	1.67	1.67
404		Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.17	1.00	1.00	1.00	1.00	
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	1.25	1.25	1.50	1.25	1.50	1.50	1.75	1.75	1.75
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	1.00	1.00	1.00	1.00
				7. Total score	6.58	6.58	6.00	5.75	5.50	5.75	5.75	5.75	5.75
405		Placebo	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	1.00	1.00	0.67	0.67	0.50	0.50	
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.50	0.17	0.67	0.00	0.00	0.00
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.00	2.00	1.50	1.75	1.00	1.00	0.75	0.75	0.75

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 12.1

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	405	Placebo	Female	6.SLEEP DISTURBANCE	1.33	1.33	1.00	0.33	0.67	0.33	0.33
				7.Total score	6.33	6.33	5.50	2.17	2.33	1.58	1.08
406	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	0.50	0.33	0.33	0.33	0.67
			2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.33	0.50	0.17	0.33	0.33
			4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
			5.RETARDATION	2.25	2.25	1.50	1.00	0.75	0.50	0.50	0.75
			6.SLEEP DISTURBANCE	0.67	0.67	0.67	1.33	0.67	0.67	0.33	0.67
			7.Total score	7.42	7.42	3.50	3.50	2.25	2.00	1.33	2.42
407	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.17	0.83	0.83	0.83	0.83
			2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.83	0.67	0.50	0.33	0.50
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5.RETARDATION	2.25	2.25	2.00	2.00	1.50	1.00	1.00	1.00
			6.SLEEP DISTURBANCE	0.67	0.67	1.00	0.67	0.67	1.00	0.67	0.67
			7.Total score	7.42	7.42	5.00	4.67	3.67	3.83	2.83	3.00
408	Placebo	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.33	0.67	0.67	0.50	0.67
			2.WEIGHT	0.00	0.00	1.00	1.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.83	0.50	0.67	0.33	0.50
			4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
			5.RETARDATION	2.75	2.75	2.75	2.75	1.75	1.50	1.25	1.00
			6.SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	0.67	0.67	0.67	0.67
			7.Total score	7.25	7.25	7.75	7.58	4.58	3.75	3.75	2.83
418	Placebo	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.00	0.83	1.00	0.67	0.33
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.83	0.67	0.67	0.17	0.00
			4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
			5.RETARDATION	2.00	2.00	1.75	2.00	1.75	1.50	1.00	0.75
			6.SLEEP DISTURBANCE	1.67	1.67	1.33	1.00	1.00	1.00	0.67	0.67
			7.Total score	7.00	7.00	6.25	5.83	5.25	5.17	2.50	1.75
419	Placebo	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.67	1.17	1.50	1.00	1.17	0.50
			2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.67	0.67	0.33	0.67	0.50	0.17	0.33	0.50
			4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	1.00	1.00	0.00	0.00
			5.RETARDATION	1.50	1.50	1.25	1.50	1.25	1.00	1.25	1.00
			6.SLEEP DISTURBANCE	1.33	1.33	0.67	1.33	1.00	1.00	0.33	0.67
			7.Total score	7.83	7.83	3.92	4.67	4.25	4.17	3.08	2.67

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
1	1	Imipramine	Female	1	01.REPORTED SADNESS	3	3	1	1	1	1	0
					02.INNER TENSION	2	2	2	1	1	1	1
					03.APPARENT SADNESS	3	2	1	1	0	0	0
					04.SUICIDAL THOUGHTS	2	2	1	0	0	0	0
					05.INERTIA	3	2	1	0	1	1	0
					06.INABILITY TO FEEL	3	2	1	1	0	0	0
					07.PESSIMISTIC THOUGHTS	2	2	1	2	1	1	0
					08.CONCENTRATIONS DIFFICULTIES	3	3	1	1	1	0	1
					09.REDUCED SLEEP	3	2	2	3	2	0	0
					10.REDUCED APPETITE	2	3	1	1	0	0	0
					11.Total score	26	23	12	11	7	5	2
2	2	Reboxetine	Male	1	01.REPORTED SADNESS	3	3	1	2	2	1	1
					02.INNER TENSION	2	2	1	1	2	1	1
					03.APPARENT SADNESS	3	3	1	2	2	1	1
					04.SUICIDAL THOUGHTS	3	3	2	2	2	0	1
					05.INERTIA	3	3	2	2	1	0	1
					06.INABILITY TO FEEL	3	3	2	1	1	1	1
					07.PESSIMISTIC THOUGHTS	3	2	2	1	2	1	1
					08.CONCENTRATIONS DIFFICULTIES	3	2	2	2	2	1	1
					09.REDUCED SLEEP	2	2	2	3	2	2	2
					10.REDUCED APPETITE	2	2	1	1	1	1	0
					11.Total score	26	24	16	15	17	9	10
3	3	Imipramine	Male	1	01.REPORTED SADNESS	2	1	2	1	1	1	0
					02.INNER TENSION	2	1	1	2	1	0	0
					03.APPARENT SADNESS	2	1	1	1	1	1	1
					04.SUICIDAL THOUGHTS	1	1	0	1	0	0	0
					05.INERTIA	2	1	2	1	1	1	1
					06.INABILITY TO FEEL	1	1	1	1	1	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	2	1	0	1	0
					09.REDUCED SLEEP	1	0	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	1	1	1	0
					11.Total score	15	9	12	10	7	6	4
4	4	Placebo	Male	1	01.REPORTED SADNESS	2	2	0	0	0	0	0
					02.INNER TENSION	1	1	1	1	0	0	0
					03.APPARENT SADNESS	2	1	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0
					05.INERTIA	1	0	0	1	0	0	0
					06.INABILITY TO FEEL	2	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	0	1	1	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	0	0
					09.REDUCED SLEEP	2	1	1	1	0	1	1
					10.REDUCED APPETITE	1	1	0	0	0	0	0
					11.Total score	16	9	6	6	3	2	2

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centro	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	5	Reboxetine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2	2	2	2	2	2	2
6		Placebo	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2	2	2	1	1	1	1
7		Reboxetine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2	1	1	1	1	0	0
8		Placebo	Male	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE	2	2	1	1	1	1	1

1311

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	8	Placebo	Male	1	11.Total score	14	13	6	5	5	3	4
					01.APPARENT SADNESS	5	4	3	5	3	3	1
					02.REPORTED SADNESS	4	4	3	4	3	1	2
					03.INNER TENSION	4	3	3	4	3	3	2
					04.REDUCED SLEEP	5	3	4	6	3	3	2
					05.REDUCED APPETITE	3	3	3	1	2	2	0
					06.CONCENTRATIONS DIFFICULTIES	4	3	4	5	3	2	3
					07.LASSITUDE	4	4	3	4	2	2	1
					08.INABILITY TO FEEL	5	4	4	4	2	2	2
					09.PESSIMISTIC THOUGHTS	5	4	4	6	2	2	1
					10.SUICIDAL THOUGHTS	4	2	4	4	2	2	1
					11.Total score	43	34	35	43	25	21	14
10		Placebo	Male	1	01.REPORTED SADNESS	2	2	1	2	2	1	1
					02.INNER TENSION	2	1	1	1	2	1	1
					03.APPARENT SADNESS	2	1	1	2	1	1	1
					04.SUICIDAL THOUGHTS	1	1	0	1	0	0	0
					05.INERTIA	2	1	1	2	1	2	0
					06.INABILITY TO FEEL	4	1	1	4	1	1	1
					07.PESSIMISTIC THOUGHTS	2	1	0	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	2	1	1	1
					09.REDUCED SLEEP	2	2	1	1	0	0	0
					10.REDUCED APPETITE	0	0	0	1	0	0	0
					11.Total score	16	11	7	14	9	8	7
11		Imipramine	Female	1	01.REPORTED SADNESS	1						
					02.INNER TENSION	2						
					03.APPARENT SADNESS	2						
					04.SUICIDAL THOUGHTS	1						
					05.INERTIA	2						
					06.INABILITY TO FEEL	2						
					07.PESSIMISTIC THOUGHTS	2						
					08.CONCENTRATIONS DIFFICULTIES	3						
					09.REDUCED SLEEP	2						
					10.REDUCED APPETITE	3						
					11.Total score	20						
12		Imipramine	Female	2	01.APPARENT SADNESS	5	3	2	2	1	0	0
					02.REPORTED SADNESS	3	3	2	2	0	0	0
					03.INNER TENSION	4	4	3	2	1	2	1
					04.REDUCED SLEEP	0	0	0	0	1	0	1
					05.REDUCED APPETITE	3	3	0	0	0	0	1
					06.CONCENTRATIONS DIFFICULTIES	5	4	3	3	2	0	1
					07.LASSITUDE	4	4	1	4	1	1	1
					08.INABILITY TO FEEL	4	3	1	1	0	0	0
					09.PESSIMISTIC THOUGHTS	2	4	0	0	1	0	0

1312

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
1	12	Imipramine	Female	2	10. SUICIDAL THOUGHTS	3	3	0	0	0	0	0	0				
					11. Total score	33	31	12	14	7	4	6					
					412	Reboxetine	Male	2	01. APPARENT SADNESS	5	4	4	3	2	1	1	1
									02. REPORTED SADNESS	4	3	3	3	1	1	0	
									03. INNER TENSION	4	2	3	3	3	1	1	
									04. REDUCED SLEEP	4	1	4	4	4	1	0	
									05. REDUCED APPETITE	4	3	1	0	3	0	0	
									06. CONCENTRATIONS DIFFICULTIES	4	3	3	2	2	0	1	
									07. LASSITUDE	4	3	4	4	4	0	1	
									08. INABILITY TO FEEL	4	3	4	3	2	0	0	
									09. PESSIMISTIC THOUGHTS	4	4	2	2	1	0	0	
10. SUICIDAL THOUGHTS	4	1	1	2					0	0	0						
11. Total score	41	27	29	26	22	4	4										
413	Placebo	Male	2	01. APPARENT SADNESS	4	2	2	2	2	3	2	2					
				02. REPORTED SADNESS	4	2	2	3	2	3	2						
				03. INNER TENSION	3	2	2	3	2	3	2						
				04. REDUCED SLEEP	4	1	4	2	0	0	0						
				05. REDUCED APPETITE	2	1	0	0	0	0	0						
				06. CONCENTRATIONS DIFFICULTIES	4	2	2	2	3	3	3						
				07. LASSITUDE	4	1	1	2	2	3	3						
				08. INABILITY TO FEEL	4	1	1	2	2	2	2						
				09. PESSIMISTIC THOUGHTS	3	1	1	2	2	3	2						
				10. SUICIDAL THOUGHTS	3	1	1	1	1	2	1						
				11. Total score	35	14	18	18	22	17							
414	Imipramine	Female	2	01. APPARENT SADNESS	4	3	4	4	4	4	0	0					
				02. REPORTED SADNESS	3	3	4	4	4	0	0						
				03. INNER TENSION	4	4	4	3	4	2	2						
				04. REDUCED SLEEP	5	4	6	6	4	4	4						
				05. REDUCED APPETITE	3	3	6	4	4	4	4						
				06. CONCENTRATIONS DIFFICULTIES	4	4	4	4	4	4	4						
				07. LASSITUDE	4	5	4	4	4	4	4						
				08. INABILITY TO FEEL	4	3	4	4	4	4	4						
				09. PESSIMISTIC THOUGHTS	3	3	2	2	1	1	1						
				10. SUICIDAL THOUGHTS	2	1	1	1	1	2	1						
				11. Total score	36	38	38	38	22	17							
415	Imipramine	Male	2	01. APPARENT SADNESS	3	2	2	2	1	0	0	0					
				02. REPORTED SADNESS	3	2	2	1	2	0	0						
				03. INNER TENSION	4	4	5	3	1	2	2						
				04. REDUCED SLEEP	4	6	2	4	4	4	4						
				05. REDUCED APPETITE	2	2	1	0	0	0	0						
				06. CONCENTRATIONS DIFFICULTIES	3	3	3	2	0	1	0						
				07. LASSITUDE	4	3	1	1	1	1	1						
				08. INABILITY TO FEEL	4	3	2	1	2	0	0						

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5

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
1	415	Imipramine	Male	2	09.PESSIMISTIC THOUGHTS	2	2	1	1	1	0	0	
					10.SUICIDAL THOUGHTS	2	1	0	0	0	0	0	
					11.Total score	31	28	17	15	12	8	7	
	416	Reboxetine	Female	2	01.APPARENT SADNESS	3	3	3	3	3	3	3	3
					02.REPORTED SADNESS	3	3	3	3	3	3	3	
					03.INNER TENSION	5	4	4	4	4	4	4	
					04.REDUCED SLEEP	4	5	4	4	4	4	4	
					05.REDUCED APPETITE	2	3	2	2	2	2	2	
					06.CONCENTRATIONS DIFFICULTIES	3	3	4	4	4	4	4	
					07.LASSITUDE	3	3	4	4	4	4	4	
					08.INABILITY TO FEEL	3	3	3	3	3	3	3	
09.PESSIMISTIC THOUGHTS					3	3	3	3	3	3	3		
10.SUICIDAL THOUGHTS					3	3	2	2	2	2	2		
11.Total score					32	34	30	30	30	30	30		
421	Imipramine	Male	2	01.APPARENT SADNESS	4	4	4	3	3	2	1	1	
				02.REPORTED SADNESS	4	4	3	2	2	1	1		
				03.INNER TENSION	3	3	2	2	2	1	1		
				04.REDUCED SLEEP	6	4	2	2	1	1	1		
				05.REDUCED APPETITE	2	3	2	2	0	0	0		
				06.CONCENTRATIONS DIFFICULTIES	3	3	3	3	1	1	2		
				07.LASSITUDE	3	4	3	2	1	2	4		
				08.INABILITY TO FEEL	3	3	2	2	0	0	0		
				09.PESSIMISTIC THOUGHTS	5	4	2	1	0	0	0		
				10.SUICIDAL THOUGHTS	4	4	1	2	0	0	0		
				11.Total score	37	36	23	21	7	7	12		
422	Imipramine	Male	2	01.APPARENT SADNESS	3	3	3	2	2	2	2	1	
				02.REPORTED SADNESS	3	3	3	2	2	2	1		
				03.INNER TENSION	3	3	2	1	1	1	1		
				04.REDUCED SLEEP	3	2	0	0	2	2	0		
				05.REDUCED APPETITE	2	2	0	0	2	2	0		
				06.CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	2	0		
				07.LASSITUDE	3	2	1	2	1	0	0		
				08.INABILITY TO FEEL	3	2	0	0	0	0	0		
				09.PESSIMISTIC THOUGHTS	2	2	1	0	0	0	0		
				10.SUICIDAL THOUGHTS	1	1	0	0	0	0	0		
				11.Total score	26	23	11	11	12	11	3		
2/1	49	Placebo	Female	1	01.REPORTED SADNESS	3	2	1	0	0	0	0	
					02.INNER TENSION	2	2	1	0	0	0	0	
					03.APPARENT SADNESS	3	2	1	0	0	0	0	
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	
					05.ENERGIA	2	2	1	0	0	0	0	
					06.INABILITY TO FEEL	1	1	0	0	0	0	0	
					07.PESSIMISTIC THOUGHTS	1	1	0	0	0	0	0	

1314

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6

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/1	49	Placebo	Female	1	08.CONCENTRATIONS DIFFICULTIES	2	2	1	0	0	0	0
					09.REDUCED SLEEP	2	2	2	2	2	1	1
					10.REDUCED APPETITE	2	2	1	0	0	0	0
					11.Total score	19	17	8	2	2	1	1
50	Reboxetine	Female	1	01.REPORTED SADNESS	2	1	0	0	0	0	0	0
				02.INNER TENSION	1	0	1	0	0	0	0	0
				03.APPARENT SADNESS	2	1	1	1	0	0	0	
				04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	
				05.INERTIA	1	1	0	0	0	0	0	
				06.INABILITY TO FEEL	1	0	0	0	0	0	0	
				07.PESSIMISTIC THOUGHTS	1	1	1	0	0	0	0	
				08.CONCENTRATIONS DIFFICULTIES	1	0	0	0	0	0	0	
				09.REDUCED SLEEP	2	2	2	2	1	1	1	
				10.REDUCED APPETITE	0	0	0	0	0	0	0	
				11.Total score	11	6	4	3	1	1	1	
51	Imipramine	Female	1	01.REPORTED SADNESS	2	1	1	1	1	0	0	0
				02.INNER TENSION	2	2	1	0	2	2	0	
				03.APPARENT SADNESS	2	1	0	0	0	0	0	
				04.SUICIDAL THOUGHTS	2	1	0	0	0	0	0	
				05.INERTIA	2	2	1	0	0	0	0	
				06.INABILITY TO FEEL	2	1	1	0	0	0	0	
				07.PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0	
				08.CONCENTRATIONS DIFFICULTIES	2	2	1	0	0	0	0	
				09.REDUCED SLEEP	2	2	2	2	2	2	2	
				10.REDUCED APPETITE	2	0	0	0	0	0	0	
				11.Total score	20	13	8	4	4	4	4	
2/2	43	Imipramine	Female	1	01.REPORTED SADNESS	1	0	0	0	1	0	0
					02.INNER TENSION	1	0	0	1	1	0	0
					03.APPARENT SADNESS	3	0	1	1	1	1	1
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0
					05.INERTIA	3	1	1	1	0	0	0
					06.INABILITY TO FEEL	1	0	1	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	0	0	0	0	1
					09.REDUCED SLEEP	2	0	1	1	1	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0
					11.Total score	16	3	4	4	4	2	2
44	Imipramine	Female	1	01.REPORTED SADNESS	1	1	1	1	1	0	1	0
				02.INNER TENSION	2	2	1	1	1	1	2	
				03.APPARENT SADNESS	2	1	1	0	0	1	0	
				04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	
				05.INERTIA	1	1	0	0	0	0	0	
				06.INABILITY TO FEEL	0	2	0	0	0	0	0	

1315

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7

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/2	44	Imipramine	Female	1	07. PESSIMISTIC THOUGHTS	2	1	1	1	1	2	2
					08. CONCENTRATIONS DIFFICULTIES	2	0	2	2	1	2	2
					09. REDUCED SLEEP	1	2	2	1	1	2	1
					10. REDUCED APPETITE	0	2	0	0	0	0	0
11. Total score						11	12	8	6	4	9	7
45	Reboxetine	Female	1	01. REPORTED SADNESS	1	1	1	1	1	0	1	1
				02. INNER TENSION	1	2	0	1	1	1	1	
				03. APPARENT SADNESS	1	1	0	1	1	0	1	
				04. SUICIDAL THOUGHTS	1	1	0	0	0	0	0	
				05. INERTIA	2	1	1	2	3	1	0	
				06. INABILITY TO FEEL	2	2	0	0	0	0	0	
				07. PESSIMISTIC THOUGHTS	1	1	2	1	1	1	1	
				08. CONCENTRATIONS DIFFICULTIES	2	0	1	0	1	0	0	
				09. REDUCED SLEEP	1	1	1	1	0	0	0	
				10. REDUCED APPETITE	0	0	0	0	0	0	0	
				11. Total score						12	10	6
46	Placebo	Female	1	01. REPORTED SADNESS	2	1	1	1	1	0	0	0
				02. INNER TENSION	2	0	1	1	1	1	1	
				03. APPARENT SADNESS	2	1	0	1	0	0	0	
				04. SUICIDAL THOUGHTS	2	0	0	0	0	0	0	
				05. INERTIA	2	2	2	2	0	0	0	
				06. INABILITY TO FEEL	2	2	2	1	0	0	0	
				07. PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0	
				08. CONCENTRATIONS DIFFICULTIES	3	2	1	1	1	1	1	
				09. REDUCED SLEEP	2	0	0	1	1	1	0	
				10. REDUCED APPETITE	0	0	0	0	0	0	0	
				11. Total score						19	9	6
47	Placebo	Female	1	01. REPORTED SADNESS	2	2	1	1	1	2	2	2
				02. INNER TENSION	2	1	1	2	2	2	1	
				03. APPARENT SADNESS	2	1	1	1	2	2	2	
				04. SUICIDAL THOUGHTS	1	1	1	0	1	1	1	
				05. INERTIA	2	1	2	1	2	2	2	
				06. INABILITY TO FEEL	2	2	3	2	2	4	1	
				07. PESSIMISTIC THOUGHTS	1	2	1	1	1	1	1	
				08. CONCENTRATIONS DIFFICULTIES	1	2	2	2	2	2	2	
				09. REDUCED SLEEP	2	2	1	1	1	1	1	
				10. REDUCED APPETITE	1	1	1	1	0	2	1	
				11. Total score						16	15	14
48	Reboxetine	Female	1	01. REPORTED SADNESS	3	2	3	1	1	1	0	1
				02. INNER TENSION	2	2	2	1	2	1	1	
				03. APPARENT SADNESS	3	2	3	1	2	1	1	
				04. SUICIDAL THOUGHTS	1	1	1	0	0	0	0	
				05. INERTIA	3	2	3	0	0	1	1	

1316

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8

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42						
2/2	48	Reboxetine	Female	1	06.INABILITY TO FEEL	2	1	2	1	1	0	1					
					07.PESSIMISTIC THOUGHTS	2	1	1	0	1	0	1					
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	0	1	0	0					
					09.REDUCED SLEEP	2	2	2	0	2	1	2					
					10.REDUCED APPETITE	1	1	0	0	0	0	0					
					11.Total score	21	16	18	4	11	4	8					
					2/3	36/A	Imipramine	Male	1	01.REPORTED SADNESS	2	2	1	1	1	1	1
										02.INNER TENSION	2	2	3	3	3	2	2
										03.APPARENT SADNESS	3	3	1	0	0	0	0
										04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0
										05.INERTIA	2	2	1	0	0	0	0
06.INABILITY TO FEEL	2	2	1	0						0	0	0					
07.PESSIMISTIC THOUGHTS	2	2	0	0						0	0	0					
08.CONCENTRATIONS DIFFICULTIES	2	2	1	1						1	1	1					
09.REDUCED SLEEP	2	2	1	1						1	1	1					
10.REDUCED APPETITE	1	1	1	0						0	0	0					
11.Total score	18	18	10	5						5	4	4					
37		Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1	1	1					
					02.INNER TENSION	2	3	3	2	2	2	2					
					03.APPARENT SADNESS	2	2	2	1	1	1	1					
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0					
					05.INERTIA	2	2	2	2	1	1	1					
					06.INABILITY TO FEEL	2	2	2	2	1	1	1					
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1					
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1					
					09.REDUCED SLEEP	2	2	2	2	1	1	1					
					10.REDUCED APPETITE	2	2	2	2	1	1	1					
					11.Total score	19	20	20	13	10	10	10					
38		Placebo	Male	1	01.REPORTED SADNESS	2	1	2	1	1	1	1					
					02.INNER TENSION	2	2	2	2	2	1	1					
					03.APPARENT SADNESS	1	0	0	0	0	0	0					
					04.SUICIDAL THOUGHTS	2	2	2	2	2	2	2					
					05.INERTIA	2	2	2	2	0	0	0					
					06.INABILITY TO FEEL	2	2	1	1	1	1	0					
					07.PESSIMISTIC THOUGHTS	2	2	3	3	2	2	1					
					08.CONCENTRATIONS DIFFICULTIES	3	3	3	2	2	2	1					
					09.REDUCED SLEEP	0	0	0	0	0	0	0					
					10.REDUCED APPETITE	19	15	15	12	10	5	6					
					11.Total score	19	15	15	12	10	5	6					
39		Imipramine	Female	1	01.REPORTED SADNESS	2	2	1	1	1	0	0					
					02.INNER TENSION	2	2	2	1	2	2	1					
					03.APPARENT SADNESS	2	2	1	1	0	0	0					
					04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0					

1317

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9

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PIRAMACIA CNS RAD
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
2/3	39	Imipramine	Female	1	05. INERTIA	2	2	2	1	1	0	0					
					06. INABILITY TO FEEL	2	2	2	0	0	0						
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	0						
					08. CONCENTRATIONS DIFFICULTIES	3	3	2	1	1	0						
					09. REDUCED SLEEP	3	3	2	1	1	0						
					10. REDUCED APPETITE	2	1	0	0	0	0						
					11. Total score	20	19	13	6	7	4	2					
					40		Reboxetine	Female	1	01. REPORTED SADNESS	1	2	2	1	1	0	0
										02. INNER TENSION	1	2	2	1	1	1	
										03. APPARENT SADNESS	2	1	1	1	1	0	
										04. SUICIDAL THOUGHTS	0	0	0	0	0	0	
05. INERTIA	0	0	0	1						1	1						
06. INABILITY TO FEEL	1	2	1	1						1	0						
07. PESSIMISTIC THOUGHTS	1	1	1	0						2	1						
08. CONCENTRATIONS DIFFICULTIES	0	0	0	0						0	0						
09. REDUCED SLEEP	1	2	2	1						2	1						
10. REDUCED APPETITE	2	1	2	2						1	0						
11. Total score	9	11	10	6						9	4	4					
41		Placebo	Male	1	01. REPORTED SADNESS	2	2	2	1	2	3	2					
					02. INNER TENSION	2	1	2	1	0	1						
					03. APPARENT SADNESS	1	2	1	2	1	1						
					04. SUICIDAL THOUGHTS	1	1	0	0	0	0						
					05. INERTIA	2	3	2	2	2	3						
					06. INABILITY TO FEEL	2	2	2	2	2	2						
					07. PESSIMISTIC THOUGHTS	2	2	1	1	1	2						
					08. CONCENTRATIONS DIFFICULTIES	1	2	2	2	2	2						
					09. REDUCED SLEEP	2	2	0	0	0	0						
					10. REDUCED APPETITE	0	0	0	0	0	0						
					11. Total score	15	17	12	11	10	14	14					
42		Imipramine	Female	1	01. REPORTED SADNESS	2	1	2	1	0	0	0					
					02. INNER TENSION	2	2	2	1	1	2						
					03. APPARENT SADNESS	2	2	1	1	1	2						
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0						
					05. INERTIA	2	2	2	0	1	1						
					06. INABILITY TO FEEL	1	1	2	1	2	0						
					07. PESSIMISTIC THOUGHTS	2	1	0	0	0	1						
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2						
					09. REDUCED SLEEP	2	1	2	2	1	0						
					10. REDUCED APPETITE	0	0	0	0	0	0						
					11. Total score	15	12	13	8	8	8	8					
2/4	31	Placebo	Male	1	01. REPORTED SADNESS	3	3	3	3	3	2	2					
					02. INNER TENSION	2	2	2	2	2	2						
					03. APPARENT SADNESS	1	1	1	1	1	1						

13
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 13

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PHARMACIA CNS R&D
 REBOZETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
2/4	31	Placebo	Male	1	04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	3 3 3 3 2 2 0 22	3 3 3 3 2 2 0 22	2 3 3 3 2 2 0 21	2 3 3 3 2 2 0 21	2 3 3 3 2 2 0 21	2 2 3 2 2 2 0 17	2 2 2 2 2 2 0 17	
	32	Rebozetine	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	3 2 3 1 2 2 3 2 0 21	3 2 3 1 2 2 3 2 0 21	3 2 3 1 2 2 3 2 0 18	2 2 2 1 1 2 3 2 0 18	2 2 2 1 1 2 3 2 0 13	1 1 2 1 1 2 1 1 0 11	0 1 1 1 1 1 1 1 0 7	
	33	Imipramine	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 3 1 1 2 3 3 0 21	2 2 3 1 1 2 3 3 0 21	2 2 3 1 1 2 3 3 0 18	2 2 3 1 1 2 3 3 0 18	1 1 2 1 1 2 3 3 0 13	1 1 0 1 1 1 0 0 0 4	1 1 0 1 1 1 0 0 0 4	
	34	Placebo	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	3 3 3 1 3 3 3 3 0 25	3 3 3 1 3 3 3 3 0 25	3 3 3 1 3 3 3 3 0 24	2 2 2 1 3 3 3 3 0 18	2 2 2 1 3 3 3 3 0 10	1 1 1 0 1 1 1 1 0 7	0 1 1 0 1 1 1 1 0 7	
	35	Rebozetine	Female	1	01. REPORTED SADNESS 02. INNER TENSION	3 2	3 2	2 3	1 2	1 2	1 2	1 1	0 0

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11

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/4	35	Reboxetine	Female	1	03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	3 3 3 2 3 2 2 23	2 2 3 3 3 3 0 22	2 2 3 2 3 2 2 22	2 2 3 2 3 2 2 17	1 1 2 2 2 1 0 14	1 1 1 1 1 1 0 9	0 0 1 1 1 1 0 6
36		Imipramine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	3 3 3 1 3 3 3 25	3 3 3 1 3 3 3 25	2 2 2 1 2 2 2 20	2 2 2 1 1 1 1 15	1 1 1 0 1 1 2 9	1 1 1 0 1 1 1 7	0 1 0 0 1 1 1 4
2/5	73	Placebo	Male	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 4 1 0 2 2 2 13	1 1 1 2 1 1 1 11	1 1 2 1 1 1 1 8	1 1 1 0 1 1 1 11	1 2 2 1 1 2 2 14	1 2 2 1 1 2 2 14	1 2 2 1 2 2 1 16
74		Reboxetine	Male	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 1 2 0 2 2 1 12	1 2 1 0 2 1 1 11	1 0 0 0 1 1 1 9	1 0 0 0 1 1 1 4	1 0 0 0 0 0 1 5	0 0 0 0 0 0 1 3	0 1 0 0 0 0 0 2
75		Imipramine	Male	1	01.REPORTED SADNESS	2	2	1	0	0	1	0

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12

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PHARMACIA CNS R&D
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/5	75	Imipramine	Male	1	02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	3	2	2	1	2	1	1
						2	2	0	0	0	0	0
						0	0	0	0	0	0	0
						2	2	0	0	1	0	0
						2	1	0	0	0	0	0
						2	2	2	1	0	0	0
						1	1	1	1	0	1	0
						2	1	2	2	0	1	1
						0	0	0	0	0	0	0
						16	13	8	5	3	4	2
	76	Imipramine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	3	2	1	2	1	1	1
						2	2	1	2	2	1	1
						2	2	0	3	0	0	1
						0	1	0	0	0	0	0
						2	2	1	2	0	1	0
						2	2	0	1	0	0	0
						2	3	0	1	0	0	0
						2	3	1	2	2	0	0
						1	1	0	1	1	0	0
						2	1	1	1	0	1	0
						2	1	1	1	0	0	0
						18	16	5	14	7	3	2
	77	Placebo	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2	1	1	1	1	0	0
						2	2	1	1	1	1	0
						1	1	0	0	0	0	0
						0	0	0	0	0	0	0
						2	1	1	1	1	0	0
						2	1	0	1	0	0	0
						2	1	1	1	0	0	0
						2	0	0	0	0	0	0
						1	1	0	0	1	0	0
						0	0	0	0	0	0	0
						14	8	4	5	4	1	0
	78	Reboxetine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2	2	2	2	1	1	1
						2	2	2	2	2	1	1
						3	0	2	1	1	0	1
						0	0	0	0	0	0	0
						1	1	2	0	1	1	1
						2	1	1	1	0	0	0
						2	2	2	2	1	0	0
						1	2	0	1	0	0	0
						1	1	1	1	0	0	0
						14	13	12	8	5	3	3

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13

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/6	55	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	0	0	0	0
					02.INNER TENSION	2	2	1	1	1	1	1
					03.APPARENT SADNESS	2	2	1	0	0	0	0
					04.SUICIDAL THOUGHTS	2	2	1	0	0	0	0
					05.INERTIA	2	2	2	1	1	1	1
					06.INABILITY TO FEEL	2	2	2	1	0	0	0
					07.PESSIMISTIC THOUGHTS	2	2	2	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1
					09.REDUCED SLEEP	3	1	1	0	0	0	0
					10.REDUCED APPETITE	1	1	1	0	0	0	0
					11.Total score	20	18	15	4	3	3	3
56	56	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1	1	2
					02.INNER TENSION	2	2	2	2	1	1	1
					03.APPARENT SADNESS	2	2	2	2	1	1	2
					04.SUICIDAL THOUGHTS	2	2	2	2	1	1	2
					05.INERTIA	2	2	2	2	2	2	3
					06.INABILITY TO FEEL	2	2	2	2	2	2	2
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1	1	2
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2
					09.REDUCED SLEEP	2	1	0	1	0	0	1
					10.REDUCED APPETITE	1	1	1	1	0	0	1
					11.Total score	19	18	17	18	11	11	19
57	57	Imipramine	Female	1	01.REPORTED SADNESS	2	2	1	0	0	0	0
					02.INNER TENSION	2	2	1	0	1	1	1
					03.APPARENT SADNESS	2	2	1	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0
					05.INERTIA	2	2	2	1	1	1	1
					06.INABILITY TO FEEL	2	2	2	1	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	3	3	2	1	1	1	1
					09.REDUCED SLEEP	2	0	0	0	0	0	0
					10.REDUCED APPETITE	1	1	1	0	1	0	0
					11.Total score	18	16	12	3	4	3	3
58	58	Placebo	Female	1	01.REPORTED SADNESS	2	2	2	0	0	0	0
					02.INNER TENSION	1	1	1	0	0	0	0
					03.APPARENT SADNESS	2	2	2	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0
					05.INERTIA	2	2	1	1	0	0	0
					06.INABILITY TO FEEL	2	2	2	1	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	1	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	2	3	1	1	1	1
					09.REDUCED SLEEP	0	0	0	0	0	0	0
					10.REDUCED APPETITE	2	2	0	0	0	0	0
					11.Total score	15	15	14	3	2	2	2

1322

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14

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/6	59	Placebo	Male	1	01.REPORTED SADNESS	2	2	2	2	2	2	2
					02.INNER TENSION	2	2	2	2	2	2	2
					03.APPARENT SADNESS	2	2	2	2	2	2	2
					04.SUICIDAL THOUGHTS	2	2	2	2	2	2	2
					05.INERTIA	3	3	3	3	3	3	3
					06.INABILITY TO FEEL	3	3	3	3	3	3	3
					07.PESSIMISTIC THOUGHTS	1	2	2	2	2	2	2
					08.CONCENTRATIONS DIFFICULTIES	3	3	2	3	3	3	3
					09.REDUCED SLEEP	2	1	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	1	1	1	1
					11.Total score	21	24	20	19	18		
60	Imipramine	Female	1	01.REPORTED SADNESS	2	2	2	1	0	0	0	0
				02.INNER TENSION	2	2	2	1	0	0	0	
				03.APPARENT SADNESS	2	2	2	1	0	0	0	
				04.SUICIDAL THOUGHTS	4	4	1	0	0	0	0	
				05.INERTIA	2	2	1	1	1	1	1	
				06.INABILITY TO FEEL	3	2	1	0	0	0	0	
				07.PESSIMISTIC THOUGHTS	2	2	1	0	0	0	0	
				08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1	
				09.REDUCED SLEEP	2	1	1	0	0	0	0	
				10.REDUCED APPETITE	1	1	0	0	0	0	0	
				11.Total score	19	16	9	2	2	2	2	
3/1	61	Imipramine	Male	1	01.REPORTED SADNESS	2	2	2	1	1	1	1
					02.INNER TENSION	2	2	2	1	1	0	0
					03.APPARENT SADNESS	1	2	1	1	0	0	0
					04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0
					05.INERTIA	2	2	2	1	0	0	0
					06.INABILITY TO FEEL	1	1	1	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1
					09.REDUCED SLEEP	2	2	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	0	0	0	0
					11.Total score	15	16	13	8	2	2	2
62	Imipramine	Female	1	01.REPORTED SADNESS	3	1	1	1	1	0	0	0
				02.INNER TENSION	2	1	1	1	1	1	1	
				03.APPARENT SADNESS	2	1	0	0	1	0	1	
				04.SUICIDAL THOUGHTS	2	1	0	0	0	0	0	
				05.INERTIA	2	1	1	1	1	1	1	
				06.INABILITY TO FEEL	2	1	1	1	1	1	1	
				07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1	
				08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	0	0	
				09.REDUCED SLEEP	3	1	0	0	0	0	0	
				10.REDUCED APPETITE	2	1	1	0	1	1	1	
				11.Total score	2	1	0	0	0	0	0	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	62	Imipramine	Female	1	11.Total score	23	10	7	5	6	4	3
	63	Placebo	Male	1	01.REPORTED SADNESS	3	3	2	2	1	1	1
					02.INNER TENSION	2	2	2	2	1	1	1
					03.APPARENT SADNESS	2	2	1	1	1	1	1
					04.SUICIDAL THOUGHTS	2	2	1	1	1	1	1
					05.INERTIA	3	3	2	2	1	1	1
					06.INABILITY TO FEEL	2	2	2	2	0	0	0
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1
					09.REDUCED SLEEP	2	2	2	2	2	1	1
					10.REDUCED APPETITE	2	2	1	1	1	1	0
					11.Total score	22	22	16	16	10	6	6
	64	Placebo	Female	1	01.REPORTED SADNESS	2	1	2	2	2	2	2
					02.INNER TENSION	2	2	2	2	2	2	2
					03.APPARENT SADNESS	2	2	2	2	2	2	2
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0
					05.INERTIA	2	2	3	3	3	3	3
					06.INABILITY TO FEEL	2	2	2	2	2	2	2
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	2	0	0	0	0	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0
					11.Total score	16	15	14	14	14	15	15
	65	Reboxetine	Male	1	01.REPORTED SADNESS	3	2	1	1	1	1	1
					02.INNER TENSION	2	1	1	1	1	1	1
					03.APPARENT SADNESS	2	2	1	1	1	1	0
					04.SUICIDAL THOUGHTS	2	1	1	0	0	0	0
					05.INERTIA	2	2	1	2	1	1	1
					06.INABILITY TO FEEL	2	2	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	1	2	1	1	0
					08.CONCENTRATIONS DIFFICULTIES	1	1	2	1	0	0	0
					09.REDUCED SLEEP	2	1	2	1	1	1	1
					10.REDUCED APPETITE	2	1	2	1	0	0	0
					11.Total score	20	14	13	9	7	5	5
	66	Reboxetine	Male	1	01.REPORTED SADNESS	2	2	1	1	1	1	1
					02.INNER TENSION	2	2	1	1	1	1	1
					03.APPARENT SADNESS	2	1	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0
					05.INERTIA	2	2	1	1	1	1	1
					06.INABILITY TO FEEL	2	2	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1
					09.REDUCED SLEEP	2	2	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	1	0	0	0
					11.Total score	1	1	1	1	0	0	0

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16

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PHARMACIA CNS R&D
 REXOXYLINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	66	Roxoxetine	Male	1	10. REDUCED APPETITE 11. Total score	2 18	2 18	1 10	1 8	0 6	0 7	0 7
	139	Imipramine	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 2 2 2 2 2 2 2 20	2 3 2 2 2 2 2 2 2 2 21	2 3 3 3 2 2 2 2 2 2 24	2 3 3 3 2 2 2 2 2 2 24	2 3 3 3 2 2 2 2 2 2 24	2 3 3 3 2 2 2 2 2 2 24	2 3 3 3 2 2 2 2 2 2 24
	140	Placebo	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 2 2 2 2 2 2 2 20	2 2 2 2 2 2 2 2 2 2 21	2 2 2 2 2 2 2 2 2 2 24	2 2 2 2 2 2 2 2 2 2 24	2 2 2 2 2 2 2 2 2 2 24	2 2 2 2 2 2 2 2 2 2 24	2 2 2 2 2 2 2 2 2 2 24
	141	Placebo	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 2 2 2 2 2 2 2 18	2 3 2 2 2 2 2 2 2 2 17	2 3 2 2 2 2 2 2 2 2 12	2 3 2 2 2 2 2 2 2 2 5	2 3 2 2 2 2 2 2 2 2 4	2 3 2 2 2 2 2 2 2 2 4	2 3 2 2 2 2 2 2 2 2 4
	142	Imipramine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES	2 2 2 2 2 2 2 2	2 3 2 2 2 2 2 2	2 3 3 2 2 2 2 2	2 3 3 2 2 2 2 2	2 3 3 2 2 2 2 2	2 3 3 2 2 2 2 2	2 3 3 2 2 2 2 2

13/25

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17

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
3/1	142	Imipramine	Female	1	09. REDUCED SLEEP	2	2	2	2					
					10. REDUCED APPETITE	2	2	2	2					
					11. Total score	21	21	21	21					
3/1	143	Reboxetine	Female	1	01. REPORTED SADNESS	2	1		1	1	1	1		
					02. INNER TENSION	2	1		1	1	1	1		
					03. APPARENT SADNESS	2	1		0	0	0	0		
					04. SUICIDAL THOUGHTS	2	1		0	0	0	0		
					05. INERTIA	1	1		1	1	1	1		
					06. INABILITY TO FEEL	1	0		0	0	0	0		
					07. PESSIMISTIC THOUGHTS	2	1		1	1	1	1		
					08. CONCENTRATIONS DIFFICULTIES	1	1		1	1	1	1		
					09. REDUCED SLEEP	1	1		1	1	1	1		
					10. REDUCED APPETITE	1	1		1	1	1	1		
					11. Total score	15	9		15	7	7	7		
3/1	144	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	1	1	0	0	0		
					02. INNER TENSION	1	2	2	2	2	1	1		
					03. APPARENT SADNESS	2	2	1	2	0	0	0		
					04. SUICIDAL THOUGHTS	2	2	0	2	0	0	0		
					05. INERTIA	2	2	1	2	1	1	1		
					06. INABILITY TO FEEL	2	2	1	2	1	1	0		
					07. PESSIMISTIC THOUGHTS	2	2	1	2	1	1	0		
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1		
					09. REDUCED SLEEP	2	3	1	2	1	1	1		
					10. REDUCED APPETITE	2	2	1	2	1	1	1		
					11. Total score	18	20	10	18	7	5	4		
3/1	451	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	2	2					
					02. INNER TENSION	2	2	3	2					
					03. APPARENT SADNESS	2	2	2	2					
					04. SUICIDAL THOUGHTS	1	0	0	0					
					05. INERTIA	2	2	2	2					
					06. INABILITY TO FEEL	2	2	2	2					
					07. PESSIMISTIC THOUGHTS	2	2	2	2					
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2					
					09. REDUCED SLEEP	2	2	3	2					
					10. REDUCED APPETITE	1	1	2	2					
					11. Total score	18	17	20	18					
3/1	452	Placebo	Male	1	01. REPORTED SADNESS	2	2	1	0	0	1	0		
					02. INNER TENSION	2	1	0	0	0	1	1		
					03. APPARENT SADNESS	2	1	0	0	0	1	1		
					04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0		
					05. INERTIA	2	1	0	0	0	0	0		
					06. INABILITY TO FEEL	2	1	0	0	0	0	0		
					07. PESSIMISTIC THOUGHTS	3	2	1	0	0	1	0		

1326

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18

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
3/1	452	Placebo	Male	1	08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	0					
					09.REDUCED SLEEP	2	1	1	1	1	1	1					
					10.REDUCED APPETITE	2	1	0	0	0	0	0					
					11.Total score	20	11	4	2	2	2	6	3				
					453	Imipramine	Female	1	01.REPORTED SADNESS	2	2	1	1	1	1	1	1
									02.INNER TENSION	2	1	1	1	0	0	1	1
									03.APPARENT SADNESS	2	1	1	1	0	0	0	0
									04.SUICIDAL THOUGHTS	2	1	0	0	0	0	0	0
									05.INERTIA	2	1	1	1	0	0	0	0
									06.INABILITY TO FEEL	2	1	1	1	0	0	0	0
									07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	0	0
08.CONCENTRATIONS DIFFICULTIES	2	2	2	2					2	2	2	1					
09.REDUCED SLEEP	2	1	1	1					1	1	1	1					
10.REDUCED APPETITE	1	1	1	1					1	1	1	1					
11.Total score	17	11	9	5					4	4	5						
13	454	Reboxetine	Male	1	01.REPORTED SADNESS	2	1	1	1	0	0	0					
					02.INNER TENSION	1	1	1	1	0	0	0	0				
					03.APPARENT SADNESS	2	1	1	1	0	0	0	0				
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0				
					05.INERTIA	2	1	1	1	0	0	0	0				
					06.INABILITY TO FEEL	2	0	0	0	0	0	0	0				
					07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1	1				
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1	1				
					09.REDUCED SLEEP	1	2	1	1	1	1	1	1				
					10.REDUCED APPETITE	1	0	0	0	0	0	0	0				
					11.Total score	15	8	7	2	2	2	4	2				
27	455	Placebo	Female	1	01.REPORTED SADNESS	2	2	2	2	2	1	1					
					02.INNER TENSION	2	2	2	2	2	2	1	1				
					03.APPARENT SADNESS	2	2	1	1	1	1	1	1				
					04.SUICIDAL THOUGHTS	2	2	1	1	1	0	0	0				
					05.INERTIA	2	2	2	2	1	1	1	1				
					06.INABILITY TO FEEL	2	2	2	2	1	1	1	1				
					07.PESSIMISTIC THOUGHTS	3	3	2	2	1	1	1	1				
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1	1				
					09.REDUCED SLEEP	1	1	1	1	1	1	1	1				
					10.REDUCED APPETITE	1	1	1	1	1	1	1	1				
					11.Total score	19	19	16	11	10	9	8					
456	Imipramine	Female	1	01.REPORTED SADNESS	2	1	1	1	1	1	1						
				02.INNER TENSION	2	2	2	2	2	2	3						
				03.APPARENT SADNESS	2	2	2	2	2	2	2						
				04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0						
				05.INERTIA	2	1	1	1	1	1	1						
				06.INABILITY TO FEEL	2	2	2	2	2	2	2						

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20

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
3/3	69	Placebo	Male	1	06. INABILITY TO FEEL	1	2	2	1	3	1	1					
					07. PESSIMISTIC THOUGHTS	2	3	2	2	2	1						
					08. CONCENTRATIONS DIFFICULTIES	3	3	1	1	2	1						
					09. REDUCED SLEEP	2	1	1	2	1							
					10. REDUCED APPETITE	1	1	1	0	1							
					11. Total score	18	20	13	8	22	9	8					
					70	Imipramine	Male	1	01. REPORTED SADNESS	2	2	2	0	1	1	1	1
									02. INNER TENSION	2	2	1	1	1	1	1	
									03. APPARENT SADNESS	2	1	1	0	0	0	0	
									04. SUICIDAL THOUGHTS	1	1	1	0	0	0	0	
									05. INERTIA	2	1	1	0	0	0	0	
06. INABILITY TO FEEL	3	1	1	1					1	1	0						
07. PESSIMISTIC THOUGHTS	2	1	1	1					1	1	0						
08. CONCENTRATIONS DIFFICULTIES	2	2	2	1					0	1	1						
09. REDUCED SLEEP	2	2	2	2					2	1	1						
10. REDUCED APPETITE	3	2	0	0					0	0	0						
11. Total score	21	15	11	4					6	4	4						
71	Imipramine	Female	1	01. REPORTED SADNESS	2	1	1	0	0	0	0	0					
				02. INNER TENSION	2	2	1	1	1	1	1						
				03. APPARENT SADNESS	1	1	0	0	0	0	0						
				04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0						
				05. INERTIA	2	1	0	0	0	0	0						
				06. INABILITY TO FEEL	1	1	1	1	1	1	0						
				07. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	1						
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	0	0	0	0						
				09. REDUCED SLEEP	0	0	0	0	0	0	0						
				10. REDUCED APPETITE	1	0	0	0	0	0	0						
				11. Total score	13	9	6	3	3	2	2						
72	Reboxetine	Male	1	01. REPORTED SADNESS	2	1	1	1	1	1	1	1					
				02. INNER TENSION	2	2	1	1	2	1	1						
				03. APPARENT SADNESS	1	1	1	0	0	0	0						
				04. SUICIDAL THOUGHTS	1	1	0	0	0	0	0						
				05. INERTIA	1	0	0	0	0	0	0						
				06. INABILITY TO FEEL	1	1	1	0	0	0	0						
				07. PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1						
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	0	0	0	0						
				09. REDUCED SLEEP	1	1	0	0	0	0	0						
				10. REDUCED APPETITE	0	0	0	0	1	1	1						
				11. Total score	12	9	5	5	6	5	7						
3/4	79	Imipramine	Female	1	01. REPORTED SADNESS	2	2	2	1	0	0	0					
					02. INNER TENSION	2	1	1	1	1	1	1					
					03. APPARENT SADNESS	2	1	1	1	1	0	0					
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0					

1329

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21

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0
MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/4	79	Imipramine	Female	1	05. INERTIA	2	2	1	0	1	0	0				
					06. INABILITY TO FEEL	2	1	1	1	1	0					
					07. PESSIMISTIC THOUGHTS	1	1	1	1	0						
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1						
					09. REDUCED SLEEP	2	2	2	1	1						
					10. REDUCED APPETITE	2	2	2	1	0						
					11. Total score	17	14	13	8	6	4	3				
					80	Imipramine	Male	1	01. REPORTED SADNESS	2	2	1	1	1		
									02. INNER TENSION	2	2	1	1			
									03. APPARENT SADNESS	2	2	1	1			
									04. SUICIDAL THOUGHTS	1	1	0	0			
05. INERTIA	1	1	1	0												
06. INABILITY TO FEEL	2	1	1	1												
07. PESSIMISTIC THOUGHTS	4	1	1	1												
08. CONCENTRATIONS DIFFICULTIES	2	2	1	0												
09. REDUCED SLEEP	2	2	2	1												
10. REDUCED APPETITE	1	0	0	0												
11. Total score	16	14	9	6												
81	Reboxetine	Female	1	01. REPORTED SADNESS	3	1	1	1	1	1	1	1				
				02. INNER TENSION	1	1	1	0	1	1	0					
				03. APPARENT SADNESS	2	1	0	0	0	0	0					
				04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0					
				05. INERTIA	2	1	0	0	0	0	0					
				06. INABILITY TO FEEL	2	1	0	0	0	0	0					
				07. PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1					
				08. CONCENTRATIONS DIFFICULTIES	3	1	0	0	0	0	0					
				09. REDUCED SLEEP	3	0	0	0	0	0	0					
				10. REDUCED APPETITE	2	1	0	0	0	0	0					
				11. Total score	21	8	3	2	3	3	2					
82	Placebo	Male	1	01. REPORTED SADNESS	2	2	1	1	1	1	1	1				
				02. INNER TENSION	1	1	1	1	1	1	1					
				03. APPARENT SADNESS	2	1	1	0	1	1	1					
				04. SUICIDAL THOUGHTS	2	1	0	0	0	0	0					
				05. INERTIA	1	1	1	1	1	1	1					
				06. INABILITY TO FEEL	1	1	0	0	0	0	0					
				07. PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1					
				08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	0	0	0					
				09. REDUCED SLEEP	2	2	1	1	1	1	1					
				10. REDUCED APPETITE	1	1	1	1	1	1	1					
				11. Total score	15	12	7	6	6	6	6					
83	Placebo	Male	1	01. REPORTED SADNESS	2	2										
				02. INNER TENSION	2	2										
				03. APPARENT SADNESS	2	2										

1330

9550082

22

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/4	83	Placebo	Male	1	04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	1 1 2 2 1 2 0 15	1 2 2 1 1 2 0 18	1 1 1 0 1 1 1 4	1 1 1 0 1 1 0 2	1 1 1 0 1 1 0 2	0 0 0 0 0 0 0 2	0 0 0 0 0 0 0 2
	84	Reboxetine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 0 1 1 1 2 2 2 15	2 1 1 0 1 1 1 4	1 1 0 0 1 1 0 2	1 1 0 0 1 1 0 2	0 0 0 0 1 1 0 2	0 0 0 0 0 0 0 2	0 1 0 0 0 1 0 2
	85	Imipramine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	3 2 2 1 2 2 2 2 2 2 19	3 1 2 0 1 2 2 2	2 1 1 0 1 1 1 2	2 1 1 0 1 1 1 2	2 1 1 0 1 1 1 2	1 1 0 0 1 1 1 2	1 0 0 0 1 1 1 2
	86	Imipramine	Male	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 1 1 2 2 2 2 2 19	2 1 2 0 1 2 2 2	1 1 1 0 1 1 1 2	1 1 1 0 1 1 1 2	0 0 0 0 0 0 0 2	0 0 0 0 0 0 0 2	0 1 1 0 0 1 1 2
	87	Placebo	Female	1	01.REPORTED SADNESS 02.INNER TENSION	2 2	2 2	2 2	2 2	3 2	2 2	2 2

1331

9550082

23

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS 88D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
3/4	87	Placebo	Female	1	03. APPARENT SADNESS	2	2	2	1	2	2	1					
					04. SUICIDAL THOUGHTS	2	1	1	0	2	2	0					
					05. INERTIA	1	1	0	0	1	1	1					
					06. INABILITY TO FEEL	2	2	1	1	2	1	1					
					07. PESSIMISTIC THOUGHTS	2	2	1	1	2	1	1					
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	2	1	1					
					09. REDUCED SLEEP	2	1	1	0	2	1	0					
					10. REDUCED APPETITE	1	0	0	0	2	1	1					
					11. Total score	17	14	11	8	20	13	10					
					1332	88	Placebo	Male	1	01. REPORTED SADNESS	2	2	1	1	1	1	1
										02. INNER TENSION	2	2	1	1	1	1	1
03. APPARENT SADNESS	1	1	1	0						0	0	0					
04. SUICIDAL THOUGHTS	0	0	0	0						0	0	0					
05. INERTIA	1	1	0	0						0	0	0					
06. INABILITY TO FEEL	2	1	1	1						1	1	1					
07. PESSIMISTIC THOUGHTS	1	0	0	0						0	0	0					
08. CONCENTRATIONS DIFFICULTIES	2	2	1	1						0	0	0					
09. REDUCED SLEEP	2	1	1	1						0	0	0					
10. REDUCED APPETITE	1	1	1	0						0	0	0					
11. Total score	14	10	7	5						3	3	3					
89	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	2	2	2	2	1	1					
				02. INNER TENSION	2	1	1	1	1	1	1						
				03. APPARENT SADNESS	2	2	2	1	1	1	0						
				04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0						
				05. INERTIA	2	1	1	1	1	1	1						
				06. INABILITY TO FEEL	2	2	2	1	1	1	1						
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1						
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	1						
				09. REDUCED SLEEP	2	2	2	2	2	2	1						
				10. REDUCED APPETITE	2	2	1	0	0	0	0						
				11. Total score	17	15	14	11	11	9	7						
90	Reboxetine	Male	1	01. REPORTED SADNESS	2	2	2	2	2	1	1	1					
				02. INNER TENSION	2	2	1	1	1	1	0						
				03. APPARENT SADNESS	2	2	1	1	1	1	1						
				04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0						
				05. INERTIA	1	1	1	1	1	1	0						
				06. INABILITY TO FEEL	2	2	2	1	1	1	1						
				07. PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1						
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	0						
				09. REDUCED SLEEP	2	1	1	1	1	1	1						
				10. REDUCED APPETITE	2	0	0	0	1	0	0						
				11. Total score	14	14	11	9	8	5	4						
457	Placebo	Female	1	01. REPORTED SADNESS	3	3	3	3	3								

9550082

24

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0
MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/4	457	Placebo	Female	1	02. INNER TENSION	2	2	2	2	2		
					03. APPARENT SADNESS	3	3	2	2	2		
					04. SUICIDAL THOUGHTS	2	2	2	2	2		
					05. INERTIA	2	2	2	2	2		
					06. INABILITY TO FEEL	2	2	2	2	2		
					07. PESSIMISTIC THOUGHTS	1	1	2	1	2		
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2		
					09. REDUCED SLEEP	2	2	2	2	2		
					10. REDUCED APPETITE	2	2	2	2	2		
					11. Total score	21	22	20	20	21		
	458	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	2	2			
					02. INNER TENSION	1	1	2	2			
					03. APPARENT SADNESS	2	2	2	2			
					04. SUICIDAL THOUGHTS	1	1	1	2			
					05. INERTIA	2	2	2	2			
					06. INABILITY TO FEEL	2	2	2	2			
					07. PESSIMISTIC THOUGHTS	1	1	1	2			
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2			
					09. REDUCED SLEEP	2	2	2	2			
					10. REDUCED APPETITE	1	1	1	2			
					11. Total score	16	17	17	20			
	459	Placebo	Female	1	01. REPORTED SADNESS	2	1	1	1	1	1	1
					02. INNER TENSION	2	2	2	2	1	1	0
					03. APPARENT SADNESS	1	1	1	1	1	1	0
					04. SUICIDAL THOUGHTS	1	1	1	0	0	0	0
					05. INERTIA	1	1	1	1	1	1	1
					06. INABILITY TO FEEL	2	2	2	1	1	1	1
					07. PESSIMISTIC THOUGHTS	2	1	1	1	0	0	0
					08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1
					09. REDUCED SLEEP	2	1	1	1	1	0	0
					10. REDUCED APPETITE	1	1	1	1	0	0	0
					11. Total score	16	13	11	9	6	5	4
	460	Reboxetine	Male	1	01. REPORTED SADNESS	1	1	1	1			
					02. INNER TENSION	1	1	1	1			
					03. APPARENT SADNESS	1	1	1	1			
					04. SUICIDAL THOUGHTS	0	0	0	0			
					05. INERTIA	2	2	2	2			
					06. INABILITY TO FEEL	2	2	2	2			
					07. PESSIMISTIC THOUGHTS	0	0	0	0			
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2			
					09. REDUCED SLEEP	3	3	3	3			
					10. REDUCED APPETITE	3	3	3	3			
					11. Total score	15	15	15	15			

1333

9550082

25

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/4	461	Imipramine	Female	1	01.REPORTED SADNESS	2	2					
					02.INNER TENSION	2	2					
					03.APPARENT SADNESS	2	1					
					04.SUICIDAL THOUGHTS	0	0					
					05.INERTIA	1	1					
					06.INABILITY TO FEEL	2	1					
					07.PESSIMISTIC THOUGHTS	1	1					
					08.CONCENTRATIONS DIFFICULTIES	2	2					
					09.REDUCED SLEEP	2	2					
					10.REDUCED APPETITE	1	1					
					11.Total score	15	13					
462	Imipramine	Female	1	01.REPORTED SADNESS	2	1						
				02.INNER TENSION	2	1						
				03.APPARENT SADNESS	2	1						
				04.SUICIDAL THOUGHTS	0	0						
				05.INERTIA	1	1						
				06.INABILITY TO FEEL	1	1						
				07.PESSIMISTIC THOUGHTS	1	1						
				08.CONCENTRATIONS DIFFICULTIES	2	1						
				09.REDUCED SLEEP	2	2						
				10.REDUCED APPETITE	1	1						
				11.Total score	15	10						
4/1	91	Imipramine	Female	1	01.REPORTED SADNESS	3	2	3	2	2	2	1
					02.INNER TENSION	2	1	2	1	1	1	0
					03.APPARENT SADNESS	2	2	2	1	1	1	1
					04.SUICIDAL THOUGHTS	2	2	2	1	1	1	0
					05.INERTIA	2	2	2	1	1	1	1
					06.INABILITY TO FEEL	2	2	2	1	1	1	0
					07.PESSIMISTIC THOUGHTS	2	1	2	1	1	1	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1
					09.REDUCED SLEEP	2	2	2	2	2	2	1
					10.REDUCED APPETITE	2	2	2	1	1	1	0
					11.Total score	21	18	20	12	12	12	5
92	Reboxetine	Female	1	01.REPORTED SADNESS	3	3	3	3	3	3	2	2
				02.INNER TENSION	2	2	2	2	2	2	2	
				03.APPARENT SADNESS	3	3	3	3	3	3	3	
				04.SUICIDAL THOUGHTS	2	2	2	1	2	2	2	
				05.INERTIA	2	2	2	2	2	2	2	
				06.INABILITY TO FEEL	2	2	2	2	2	2	2	
				07.PESSIMISTIC THOUGHTS	2	3	3	3	2	2	2	
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	
				09.REDUCED SLEEP	3	3	3	3	2	2	2	
				10.REDUCED APPETITE	2	2	2	2	2	2	2	
				11.Total score	23	24	24	23	22	21	21	

1334

9550082

26

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	93	Placebo	Male	1	01.REPORTED SADNESS	2	2	2	1	0	0	0
					02.INNER TENSION	1	2	2	1	1	1	0
					03.APPARENT SADNESS	1	2	2	2	0	0	0
					04.SUICIDAL THOUGHTS	1	1	2	1	0	0	0
					05.INERTIA	1	2	2	1	0	0	0
					06.INABILITY TO FEEL	2	2	2	2	1	1	0
					07.PESSIMISTIC THOUGHTS	1	2	2	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	2	1	0	0	0
					09.REDUCED SLEEP	1	2	2	2	1	1	0
					10.REDUCED APPETITE	0	0	0	1	0	0	0
					11.Total score	11	16	18	13	4	4	1
	94	Placebo	Female	1	01.REPORTED SADNESS	2	2	1	1	0	0	0
					02.INNER TENSION	2	2	1	0	0	0	0
					03.APPARENT SADNESS	2	2	0	0	0	0	0
					04.SUICIDAL THOUGHTS	2	1	0	0	0	0	0
					05.INERTIA	1	1	0	1	1	0	0
					06.INABILITY TO FEEL	2	2	2	1	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	0	0
					09.REDUCED SLEEP	2	2	1	0	0	0	0
					10.REDUCED APPETITE	2	2	1	0	0	0	0
					11.Total score	18	18	9	4	2	0	0
	95	Imipramine	Female	1	01.REPORTED SADNESS	2	1	1	1	1	1	0
					02.INNER TENSION	2	1	0	0	0	1	0
					03.APPARENT SADNESS	1	1	1	1	1	1	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0
					05.INERTIA	2	1	0	0	0	1	0
					06.INABILITY TO FEEL	2	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1
					09.REDUCED SLEEP	2	0	0	0	1	1	0
					10.REDUCED APPETITE	0	0	0	1	1	1	0
					11.Total score	15	6	4	4	4	6	1
	96	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	2	1	1	1	1
					02.INNER TENSION	2	2	1	1	1	1	1
					03.APPARENT SADNESS	3	2	1	1	1	1	1
					04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0
					05.INERTIA	3	1	1	1	1	1	0
					06.INABILITY TO FEEL	2	2	2	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1
					09.REDUCED SLEEP	2	2	2	1	1	1	1
					10.REDUCED APPETITE	2	2	2	1	1	1	1
					11.Total score	2	2	2	1	1	1	1

1335

9550082

27

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	96	Reboxetine	Female	1	11.Total score	22	19	15	10	9	9	9
	115	Reboxetine	Female	1	01.REPORTED SADNESS	2	1	1	1	1	1	1
					02.INNER TENSION	2	2	1	1	1	1	1
					03.APPARENT SADNESS	2	1	1	1	1	1	1
					04.SUICIDAL THOUGHTS	1	1	1	1	1	1	0
					05.INERTIA	2	1	1	1	1	1	1
					06.INABILITY TO FEEL	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1	1	0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	1	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	1	1	1	1
					11.Total score	16	12	11	11	10	10	8
	116	Imipramine	Female	1	01.REPORTED SADNESS	2	2					
					02.INNER TENSION	2	2					
					03.APPARENT SADNESS	2	2					
					04.SUICIDAL THOUGHTS	1	1					
					05.INERTIA	2	2					
					06.INABILITY TO FEEL	2	2					
					07.PESSIMISTIC THOUGHTS	2	2					
					08.CONCENTRATIONS DIFFICULTIES	2	2					
					09.REDUCED SLEEP	2	2					
					10.REDUCED APPETITE	1	1					
					11.Total score	18	16					
	117	Imipramine	Female	1	01.REPORTED SADNESS	2	2	1	1	1	1	1
					02.INNER TENSION	2	1	1	0	0	0	0
					03.APPARENT SADNESS	3	2	1	1	1	1	1
					04.SUICIDAL THOUGHTS	2	1	1	1	1	1	1
					05.INERTIA	2	2	1	1	1	1	1
					06.INABILITY TO FEEL	3	2	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	3	2	1	1	1	1	1
					09.REDUCED SLEEP	2	2	1	0	0	0	0
					10.REDUCED APPETITE	2	2	0	0	0	0	0
					11.Total score	23	18	9	7	7	7	7
	118	Reboxetine	Female	1	01.REPORTED SADNESS	1	1	1	1	1	1	1
					02.INNER TENSION	1	1	1	1	1	1	1
					03.APPARENT SADNESS	1	1	1	1	1	1	1
					04.SUICIDAL THOUGHTS	2	1	1	1	0	0	0
					05.INERTIA	2	2	1	1	1	1	1
					06.INABILITY TO FEEL	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1
					09.REDUCED SLEEP	2	2	1	1	1	1	1
					11.Total score	2	2	1	1	1	1	1

1336

9550082

23

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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 REBOXETINE - PROTOCOL 20124/015
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 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
4/1	118	Reboxetine	Female	1	10. REDUCED APPETITE	1	1	1	1	0	0	0	
					11. Total score	15	14	10	10	8	8	8	
119	Placebo	Female	1	01. REPORTED SADNESS	2								
				02. INNER TENSION	1								
				03. APPARENT SADNESS	3								
				04. SUICIDAL THOUGHTS	0								
				05. INERTIA	2								
				06. INABILITY TO FEEL	2								
				07. PESSIMISTIC THOUGHTS	2								
				08. CONCENTRATIONS DIFFICULTIES	2								
				09. REDUCED SLEEP	2								
				10. REDUCED APPETITE	1								
				11. Total score	17								
120	Placebo	Female	1	01. REPORTED SADNESS	2	2	1	1	1	1	1	1	
				02. INNER TENSION	2	1	1	1	1	1	1	1	1
				03. APPARENT SADNESS	1	1	1	1	0	0	0	0	0
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1	1	1
				05. INERTIA	2	2	1	1	1	1	1	1	1
				06. INABILITY TO FEEL	2	2	2	1	1	1	1	1	1
				07. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	1	1	1
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1	1
				09. REDUCED SLEEP	1	1	1	1	1	1	1	1	1
				10. REDUCED APPETITE	1	1	1	1	1	1	1	1	1
				11. Total score	15	14	11	9	7	7	6		
145	Imipramine	Female	1	01. REPORTED SADNESS	2	1	1	1	1	1	1	1	
				02. INNER TENSION	2	1	1	1	1	1	1	1	
				03. APPARENT SADNESS	2	2	1	1	1	1	1	0	
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	0	0	
				05. INERTIA	1	1	1	1	1	1	1	1	
				06. INABILITY TO FEEL	2	1	1	1	1	1	1	1	
				07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1	1	
				08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1	1	
				09. REDUCED SLEEP	2	2	1	1	1	1	1	1	
				10. REDUCED APPETITE	2	2	1	1	1	1	0	0	
				11. Total score	18	13	10	9	6	6	6		
146	Placebo	Female	1	01. REPORTED SADNESS	2	2	2	1	1	1	1	1	
				02. INNER TENSION	2	2	1	1	1	1	1	0	
				03. APPARENT SADNESS	2	2	2	1	1	1	1	1	
				04. SUICIDAL THOUGHTS	2	1	1	1	1	1	1	1	
				05. INERTIA	2	1	1	1	1	1	1	1	
				06. INABILITY TO FEEL	2	2	2	1	1	1	1	1	
				07. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	1	1	
				08. CONCENTRATIONS DIFFICULTIES	3	2	2	2	1	1	1	1	

1337

9550082

29

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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 REBOXETINE - PROTOCOL 20124/015
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 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	146	Placebo	Female	1	09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 21	2 1 17	1 1 15	1 1 11	1 1 10	1 1 9	0 0 7
	147	Reboxetine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 1 2 2 2 2 2 2 18	2 2 1 2 2 2 2 2 2 2 17	2 2 1 2 2 2 2 2 2 2 16	2 2 1 1 1 2 2 2 2 2 12	1 1 1 1 1 1 1 1 1 1 9	1 1 1 1 1 2 1 1 1 1 10	1 1 1 0 1 1 1 1 1 1 8
	148	Imipramine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 2 2 2 3 2 2 2 21	2 1 2 1 2 2 2 2 2 2 16	2 1 1 0 1 1 2 2 2 2 14	1 1 1 0 1 1 2 2 2 2 9	1 1 1 0 1 1 1 1 1 1 8	1 1 1 0 1 1 1 1 1 1 7	
	149	Reboxetine	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 2 2 2 2 2 2 2 18	2 2 1 2 2 2 2 2 2 2 17	1 2 1 1 1 1 1 1 1 1 12	1 1 1 1 1 1 1 1 1 1 10	1 1 1 1 1 1 1 1 1 1 7	0 0 0 0 1 1 1 1 1 1 6	
	150	Placebo	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS	2 2 2 1 2 2 2	2 2 1 1 1 1 2	1 1 1 1 1 1 2	1 1 1 1 1 1 2	1 1 1 1 1 1 2	1 1 1 1 1 1 2	1 0 0 0 1 1 1

1338

9550082

30

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

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 REBOXETINE - PROTOCOL 20124/015
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 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	150	Placebo	Male	1	08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1
					09. REDUCED SLEEP	2	1	1	1	1	1	1
					10. REDUCED APPETITE	1	0	0	0	0	0	0
					11. Total score	18	13	11	10	9	8	7
					01. REPORTED SADNESS	3	3	3	1	0	0	0
					02. INNER TENSION	2	2	2	1	1	0	0
					03. APPARENT SADNESS	3	3	3	1	0	0	0
					04. SUICIDAL THOUGHTS	2	2	2	1	0	0	0
					05. INERTIA	2	2	2	2	1	0	0
					06. INABILITY TO FEEL	2	2	2	2	1	0	0
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	0	0
4/2	93/A	Placebo	Male	1	08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	0
					09. REDUCED SLEEP	2	2	2	2	1	0	0
					10. REDUCED APPETITE	2	2	2	2	1	0	0
					11. Total score	24	21	21	12	5	1	0
					01. REPORTED SADNESS	2	2	2	1	1	0	0
					02. INNER TENSION	3	3	3	1	0	0	0
					03. APPARENT SADNESS	2	2	2	1	1	0	0
					04. SUICIDAL THOUGHTS	2	2	2	2	1	0	0
					05. INERTIA	2	2	2	2	1	0	0
					06. INABILITY TO FEEL	2	2	2	2	1	0	0
					07. PESSIMISTIC THOUGHTS	2	2	2	2	1	0	0
99/A	Placebo	Male	1	08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	0	
				09. REDUCED SLEEP	2	2	2	2	1	0	0	
				10. REDUCED APPETITE	2	2	2	2	1	0	0	
				11. Total score	24	21	21	12	5	1	0	
				01. REPORTED SADNESS	2	2	2	1	1	0	0	
				02. INNER TENSION	2	2	2	1	1	1	0	
				03. APPARENT SADNESS	2	2	2	1	1	1	0	
				04. SUICIDAL THOUGHTS	2	2	2	1	1	1	0	
				05. INERTIA	2	2	2	1	1	1	0	
				06. INABILITY TO FEEL	2	2	2	1	1	1	0	
				07. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	0	
104	Reboxetine	Male	1	08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	
				09. REDUCED SLEEP	2	2	2	2	2	2	2	
				10. REDUCED APPETITE	2	2	2	2	2	2	2	
				11. Total score	19	18	9	9	8	2	0	
				01. REPORTED SADNESS	3	3	2	2	2	2	2	
				02. INNER TENSION	2	2	2	2	2	2	2	
				03. APPARENT SADNESS	2	2	2	2	2	2	2	
				04. SUICIDAL THOUGHTS	2	2	2	2	2	2	2	
				05. INERTIA	2	2	2	2	2	2	2	
				06. INABILITY TO FEEL	2	2	2	2	2	2	2	
				07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2	
4/3	97	Placebo	Male	1	08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2
					09. REDUCED SLEEP	2	2	2	2	2	2	2
					10. REDUCED APPETITE	2	2	2	2	2	2	2
					11. Total score	21	21	20	19	19	19	19
					01. REPORTED SADNESS	2	2	2	2	2	2	2
					02. INNER TENSION	1	1	1	1	1	1	1
					03. APPARENT SADNESS	3	3	3	3	3	3	3
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1
					05. INERTIA	2	2	2	2	2	2	2
					06. INABILITY TO FEEL	2	2	2	2	2	2	2
					07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2

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31

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PHARMACIA CNS R&D
 REXOXYTINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
4/3	97	Placebo	Male	1	07.FESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 1 0 16	2 2 1 0 16	2 2 1 0 16	2 2 1 0 16	2 2 1 0 17	2 2 1 0 17	2 2 1 0 17	
	98	Reboxetine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.FESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 1 3 2 3 3 2 1 23	2 2 2 1 2 2 2 2 2 1 18	2 2 2 1 1 2 2 2 2 1 15	2 2 2 1 1 2 2 2 2 1 15	2 2 2 1 1 2 2 2 2 1 15	2 2 2 1 1 2 2 2 2 1 15	3 3 3 1 2 2 2 2 2 1 21	
	99	Placebo	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.FESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 1 2 2 2 2 1 1 16	2 2 2 1 2 2 2 2 1 1 16	2 2 2 1 2 2 2 2 1 1 19	2 2 2 1 2 2 2 2 1 1 19	2 2 2 1 2 2 2 2 1 1 19	2 2 2 1 2 2 2 2 1 1 19	2 2 2 1 2 2 2 2 1 1 19	
	100	Imipramine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.FESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 1 1 2 2 2 2 2 2 17	2 2 1 1 2 2 2 2 2 2 15	2 2 2 1 2 2 2 2 2 2 20	2 2 2 1 2 2 2 2 2 2 20	2 2 2 1 2 2 2 2 2 2 20	2 2 2 1 2 2 2 2 2 2 20	2 2 2 1 2 2 2 2 2 2 20	
	101	Imipramine	Male	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA	2 2 2 1 2	2 2 2 1 2	2 2 2 1 2	2 2 2 1 2	2 2 2 1 2	2 2 2 1 2	2 2 2 1 2	0 0 0 0 1

1340

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32

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
4/3	101	Imipramine	Male	1	06. INABILITY TO FEEL	2	2	2	1	1	1	0					
					07. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	0					
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	0					
					09. REDUCED SLEEP	1	1	1	0	0	0	0					
					10. REDUCED APPETITE	1	1	1	0	0	0	0					
					11. Total score	17	17	14	8	7	4	2					
					4/4	109	Reboxetine	Female	1	01. REPORTED SADNESS	2	1	1	0	0	0	0
										02. INNER TENSION	2	1	1	1	1	1	1
										03. APPARENT SADNESS	3	2	1	0	0	0	0
										04. SUICIDAL THOUGHTS	1	1	0	0	0	0	0
										05. INERTIA	3	3	2	1	0	0	0
06. INABILITY TO FEEL	1	1	0	0						0	0	0					
07. PESSIMISTIC THOUGHTS	2	2	1	1						1	1	0					
08. CONCENTRATIONS DIFFICULTIES	3	2	1	1						0	0	0					
09. REDUCED SLEEP	2	2	1	1						1	1	0					
10. REDUCED APPETITE	2	2	0	0						0	0	0					
11. Total score	21	17	8	5						3	2	1					
1341	110	Imipramine	Male	1	04. REPORTED SADNESS	2	1	2	1	1	1	1					
					02. INNER TENSION	2	2	2	1	1	1	0					
					03. APPARENT SADNESS	3	2	2	1	1	1	1					
					06. SUICIDAL THOUGHTS	1	1	1	0	0	0	0					
					05. INERTIA	3	2	2	2	1	1	1					
					06. INABILITY TO FEEL	2	2	2	1	1	1	1					
					07. PESSIMISTIC THOUGHTS	1	1	2	1	1	1	1					
					08. CONCENTRATIONS DIFFICULTIES	3	2	2	2	1	1	1					
					09. REDUCED SLEEP	2	2	2	2	0	1	1					
					10. REDUCED APPETITE	2	2	2	2	1	1	0					
					11. Total score	21	17	19	12	8	7	8					
	111	Imipramine	Male	1	01. REPORTED SADNESS	2	2	1	1	1	1	1					
					02. INNER TENSION	2	2	1	1	1	1	1					
					03. APPARENT SADNESS	3	3	2	1	1	0	0					
					04. SUICIDAL THOUGHTS	1	1	0	0	0	0	0					
					05. INERTIA	2	3	2	1	1	1	0					
					06. INABILITY TO FEEL	2	2	2	1	1	1	0					
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0					
					08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1					
					09. REDUCED SLEEP	1	1	1	1	1	1	0					
					10. REDUCED APPETITE	2	2	2	1	1	1	0					
					11. Total score	18	19	12	9	6	6	4					
	112	Placebo	Male	1	01. REPORTED SADNESS	2	2	2	1	1	2	1					
					02. INNER TENSION	2	1	2	2	2	2	1					
					03. APPARENT SADNESS	2	1	1	1	1	2	1					
					04. SUICIDAL THOUGHTS	1	1	1	1	0	0	0					

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33

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PHARNACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centro	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
4/4	112	Placebo	Male	1	05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 1 2 2 2 2 18	1 1 2 1 1 1 14	2 2 1 1 1 1 14	2 1 1 1 1 1 12	1 1 1 2 1 1 11	2 2 2 2 2 2 17	2 2 1 2 2 1 12	
	113	Reboxetine	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 2 2 2 2 2 2 2 19	2 2 1 1 2 1 1 1 2 2 16	2 1 1 1 1 1 1 1 1 1 10	1 1 1 1 1 1 1 1 1 1 11	1 1 1 0 0 1 1 1 1 1 8	1 1 1 0 0 1 1 1 1 1 5	0 1 1 0 0 0 1 1 1 1 5	
	114	Placebo	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 1 2 2 2 2 2 2 2 16	2 2 1 1 2 2 2 2 2 2 16	1 1 0 1 1 1 1 1 1 1 10	1 2 1 1 1 1 1 1 1 1 10	1 1 0 0 1 1 1 1 1 1 6	1 1 0 0 1 1 1 1 1 1 6	1 1 0 0 0 0 1 1 1 1 6	
	175	Imipramine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	3 3 3 2 3 2 2 2 2 2 24	3 3 2 1 3 2 2 2 2 2 22	1 1 1 0 1 1 1 1 1 1 16	1 1 1 0 1 1 2 2 2 2 11	1 1 1 0 1 1 1 1 1 1 9	0 1 1 0 0 0 0 0 1 1 4	0 1 0 0 0 0 0 0 0 0 2	
	176	Placebo	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS	3 2 3	2 2 3	2 2 2	2 3 2	2 3 2	2 3 2	2 3 2	3 2 3

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

34

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/4	176	Placebo	Female	1	04.SUICIDAL THOUGHTS	1	1	0	0	3		
					05.INERTIA	2	2	2	2	3		
					06.INABILITY TO FEEL	2	2	2	2	2		
					07.PESSIMISTIC THOUGHTS	1	1	1	1	2		
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2		
					09.REDUCED SLEEP	2	2	2	2	3		
					10.REDUCED APPETITE	2	2	2	2	2		
					11.Total score	20	19	17	17	25		
	177	Imipramine	Female	1	01.REPORTED SADNESS	3	3	2				
					02.INNER TENSION	3	2	2				
					03.APPARENT SADNESS	2	3	3				
					04.SUICIDAL THOUGHTS	1	1	1				
					05.INERTIA	1	2	2				
					06.INABILITY TO FEEL	2	2	2				
					07.PESSIMISTIC THOUGHTS	2	2	2				
					08.CONCENTRATIONS DIFFICULTIES	2	2	2				
					09.REDUCED SLEEP	2	2	2				
					10.REDUCED APPETITE	2	2	2				
					11.Total score	20	21	19				
	178	Reboxetine	Female	1	01.REPORTED SADNESS	2	1	1	1	0	0	0
					02.INNER TENSION	2	2	1	1	1	1	0
					03.APPARENT SADNESS	2	1	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0
					05.INERTIA	2	1	1	1	0	0	0
					06.INABILITY TO FEEL	2	2	1	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	1	1	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	0	0	0	0
					09.REDUCED SLEEP	2	1	1	1	0	0	0
					10.REDUCED APPETITE	2	1	1	1	1	1	1
					11.Total score	19	13	8	6	3	2	2
	179	Placebo	Female	1	01.REPORTED SADNESS	3	3	2	3			
					02.INNER TENSION	3	3	2	3			
					03.APPARENT SADNESS	2	2	2	3			
					04.SUICIDAL THOUGHTS	2	1	1	3			
					05.INERTIA	2	2	2	3			
					06.INABILITY TO FEEL	2	2	2	2			
					07.PESSIMISTIC THOUGHTS	2	2	2	3			
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2			
					09.REDUCED SLEEP	2	1	1	2			
					10.REDUCED APPETITE	2	2	2	2			
					11.Total score	22	20	17	26			
	180	Reboxetine	Male	1	01.REPORTED SADNESS	2	2	1	1	1	0	0
					02.INNER TENSION	2	1	1	1	1	0	1

1343

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35

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/4	180	Reboxetine	Male	1	2	1	1	0	0	0	0
					03.APPARENT SADNESS	1	1	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0
					05.INERTIA	2	2	1	0	0	0
					06.INABILITY TO FEEL	2	2	1	1	1	0
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	0	0
					09.REDUCED SLEEP	2	2	1	1	1	1
					10.REDUCED APPETITE	2	2	1	1	1	0
					11.Total score	19	17	11	8	7	3
5/1	127	Reboxetine	Male	1	3	1	2	1	1	1	1
					01.REPORTED SADNESS	2	2	2	1	1	1
					02.INNER TENSION	3	2	2	1	1	1
					03.APPARENT SADNESS	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	2	2	1	2	1	0
					05.INERTIA	2	2	1	2	1	2
					06.INABILITY TO FEEL	2	2	1	1	1	1
					07.PESSIMISTIC THOUGHTS	3	2	2	2	1	2
					08.CONCENTRATIONS DIFFICULTIES	2	1	2	1	2	1
					09.REDUCED SLEEP	0	0	0	0	0	0
					10.REDUCED APPETITE	18	13	10	11	9	12
					11.Total score						
	128	Reboxetine	Female	1	1	1	1	1	1	1	1
					01.REPORTED SADNESS	2	1	1	1	1	2
					02.INNER TENSION	1	0	0	0	0	0
					03.APPARENT SADNESS	2	1	1	1	1	1
					04.SUICIDAL THOUGHTS	2	1	1	1	1	1
					05.INERTIA	2	1	0	0	0	0
					06.INABILITY TO FEEL	2	1	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1
					09.REDUCED SLEEP	1	0	0	0	0	0
					10.REDUCED APPETITE	15	7	6	6	7	6
					11.Total score						
	129	Placebo	Male	1	1	2	1	1	1	1	2
					01.REPORTED SADNESS	1	2	1	1	1	2
					02.INNER TENSION	1	1	2	1	1	2
					03.APPARENT SADNESS	1	1	0	0	0	1
					04.SUICIDAL THOUGHTS	2	2	1	0	0	1
					05.INERTIA	2	1	1	1	0	1
					06.INABILITY TO FEEL	1	1	1	1	1	0
					07.PESSIMISTIC THOUGHTS	1	2	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	0	1	1	1
					09.REDUCED SLEEP	2	1	0	0	0	1
					10.REDUCED APPETITE	2	1	0	0	0	1
					11.Total score	14	14	7	6	5	13
	130	Placebo	Male	1	2	2	2	2	1	1	1
					01.REPORTED SADNESS	2	2	2	2	1	1

1344

9550082

36

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
5/1	130	Placebo	Male	1	02. INNER TENSION	2	2	1	2	1	0	2
					03. APPARENT SADNESS	2	2	2	2	1	0	1
					04. SUICIDAL THOUGHTS	1	1	1	2	0	0	0
					05. INERTIA	2	2	2	2	1	1	2
					06. INABILITY TO FEEL	1	2	1	2	0	1	1
					07. PESSIMISTIC THOUGHTS	1	2	1	2	0	1	1
					08. CONCENTRATIONS DIFFICULTIES	2	2	1	2	0	1	1
					09. REDUCED SLEEP	1	0	1	2	0	0	1
					10. REDUCED APPETITE	1	1	1	1	2	0	0
					11. Total score	15	16	13	17	7	4	9
					131	131	Imipramine	Female	1	01. REPORTED SADNESS	2	2
02. INNER TENSION	2	2	1	2						1	1	1
03. APPARENT SADNESS	3	2	2	2						1	0	0
04. SUICIDAL THOUGHTS	1	1	2	2						0	0	0
05. INERTIA	2	2	2	2						1	0	0
06. INABILITY TO FEEL	2	2	2	3						1	0	0
07. PESSIMISTIC THOUGHTS	2	2	1	1						1	1	1
08. CONCENTRATIONS DIFFICULTIES	1	1	1	1						0	1	2
09. REDUCED SLEEP	1	1	1	1						1	1	0
10. REDUCED APPETITE	1	1	1	1						0	0	0
11. Total score	17	16	12	14						7	4	4
132	132	Imipramine	Male	1	01. REPORTED SADNESS	2	0	0	0	0	0	0
					02. INNER TENSION	1	0	0	0	0	0	0
					03. APPARENT SADNESS	1	0	0	0	0	0	0
					04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0
					05. INERTIA	2	0	0	0	0	0	0
					06. INABILITY TO FEEL	2	0	0	0	0	0	0
					07. PESSIMISTIC THOUGHTS	1	0	0	0	0	0	0
					08. CONCENTRATIONS DIFFICULTIES	1	0	0	0	0	0	0
					09. REDUCED SLEEP	2	1	0	0	0	0	0
					10. REDUCED APPETITE	0	0	0	0	0	0	0
					11. Total score	13	1	0	0	0	0	0
5/2	121	Imipramine	Female	1	01. REPORTED SADNESS	2	2	2	1	1	1	2
					02. INNER TENSION	2	3	3	1	1	1	1
					03. APPARENT SADNESS	2	2	2	1	1	2	2
					04. SUICIDAL THOUGHTS	2	2	2	0	1	1	2
					05. INERTIA	2	2	2	0	2	2	2
					06. INABILITY TO FEEL	2	2	2	2	2	2	1
					07. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	2
					08. CONCENTRATIONS DIFFICULTIES	3	2	2	2	2	2	2
					09. REDUCED SLEEP	2	2	2	1	1	1	1
					10. REDUCED APPETITE	2	2	3	2	2	2	3
					11. Total score	22	21	22	13	14	14	20

1345

9550082

37

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
5/2	125	Reboxetine	Male	1	01.REPORTED SADNESS	2	2	0	0	0	0	0
					02.INNER TENSION	2	2	0	1	1	1	2
					03.APPARENT SADNESS	2	2	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0
					05.INERTIA	3	2	1	0	0	1	0
					06.INABILITY TO FEEL	2	2	1	0	0	0	0
					07.PESSIMISTIC THOUGHTS	0	1	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	0	0	0	1	0
					09.REDUCED SLEEP	0	2	1	2	2	1	2
					10.REDUCED APPETITE	2	2	0	1	1	0	0
					11.Total score	16	17	3	4	4	4	4
5/3	133	Placebo	Male	1	01.REPORTED SADNESS	2	2	2	2	2	2	2
					02.INNER TENSION	2	2	2	2	2	2	2
					03.APPARENT SADNESS	2	2	2	2	2	2	2
					04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1
					05.INERTIA	1	1	1	1	1	1	1
					06.INABILITY TO FEEL	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	2	2	2	2	2	2
					10.REDUCED APPETITE	1	1	1	1	1	1	1
					11.Total score	14	16	20	20	20	20	20
134		Reboxetine	Female	1	01.REPORTED SADNESS	2	2	0	2	0	0	0
					02.INNER TENSION	2	2	1	2	0	0	1
					03.APPARENT SADNESS	1	1	0	2	0	0	0
					04.SUICIDAL THOUGHTS	1	1	0	1	0	0	0
					05.INERTIA	2	1	0	0	0	0	0
					06.INABILITY TO FEEL	2	2	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	0	1	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	0	0	0	0	0
					09.REDUCED SLEEP	2	2	2	2	2	2	1
					10.REDUCED APPETITE	1	1	0	1	0	0	1
					11.Total score	16	15	3	12	2	2	2
135		Imipramine	Female	1	01.REPORTED SADNESS	2	1	0	0	0	2	2
					02.INNER TENSION	2	1	1	1	1	1	2
					03.APPARENT SADNESS	1	0	0	0	0	1	2
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					05.INERTIA	2	1	0	0	1	2	2
					06.INABILITY TO FEEL	2	1	0	0	0	0	1
					07.PESSIMISTIC THOUGHTS	1	0	0	0	0	1	2
					08.CONCENTRATIONS DIFFICULTIES	2	1	0	0	0	1	2
					09.REDUCED SLEEP	2	1	1	1	1	1	2
					10.REDUCED APPETITE	1	0	0	0	0	0	0
					11.Total score	15	6	2	2	3	11	15

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PIARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0
MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
5/3	136	Imipramine	Female	1	01. REPORTED SADNESS	2	2	0	0	0	0	0
					02. INNER TENSION	1	1	1	0	0	0	0
					03. APPARENT SADNESS	2	1	0	0	0	0	0
					04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0
					05. INERTIA	2	2	0	0	1	0	0
					06. INABILITY TO FEEL	2	1	0	0	0	0	0
					07. PESSIMISTIC THOUGHTS	1	1	0	0	1	0	0
					08. CONCENTRATIONS DIFFICULTIES	2	2	1	0	1	0	0
					09. REDUCED SLEEP	2	2	1	2	2	1	1
					10. REDUCED APPETITE	1	1	0	0	0	0	0
					11. Total score	16	13	3	2	6	1	1
137	137	Reboxetine	Female	1	01. REPORTED SADNESS	2	1	0	0	0	0	0
					02. INNER TENSION	1	1	0	0	1	1	1
					03. APPARENT SADNESS	2	2	0	0	0	0	0
					04. SUICIDAL THOUGHTS	1	1	0	0	0	0	0
					05. INERTIA	4	1	1	0	0	0	0
					06. INABILITY TO FEEL	1	1	0	0	0	0	0
					07. PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0
					08. CONCENTRATIONS DIFFICULTIES	2	1	0	0	0	0	0
					09. REDUCED SLEEP	2	2	2	2	2	1	1
					10. REDUCED APPETITE	2	2	1	0	0	0	0
					11. Total score	17	12	4	2	3	2	2
138	138	Placebo	Female	1	01. REPORTED SADNESS	2	2	0	0	0	0	0
					02. INNER TENSION	1	1	0	0	0	0	0
					03. APPARENT SADNESS	2	2	0	0	0	0	0
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					05. INERTIA	2	2	0	0	0	0	0
					06. INABILITY TO FEEL	1	1	0	0	0	0	0
					07. PESSIMISTIC THOUGHTS	1	1	0	0	0	0	0
					08. CONCENTRATIONS DIFFICULTIES	2	2	0	0	0	0	0
					09. REDUCED SLEEP	2	2	2	2	2	1	1
					10. REDUCED APPETITE	1	1	1	0	0	0	0
					11. Total score	14	14	4	2	3	2	2
6/1	151	Imipramine	Male	1	01. REPORTED SADNESS	2	2	0	0	0	0	0
					02. INNER TENSION	2	1	0	0	0	0	0
					03. APPARENT SADNESS	2	2	0	0	0	0	0
					04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0
					05. INERTIA	1	1	0	0	0	0	0
					06. INABILITY TO FEEL	2	2	0	0	0	0	0
					07. PESSIMISTIC THOUGHTS	1	1	0	0	0	0	0
					08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	0	0	0
					09. REDUCED SLEEP	3	3	3	3	3	3	3
					10. REDUCED APPETITE	2	2	1	1	1	1	1
					11. Total score	2	2	1	1	1	1	1

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39

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/1	151	Imipramine	Male	1	11.Total score	17	14					
	152	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	2	1	1	1	0
					02.INNER TENSION	2	2	1	1	1	1	0
					03.APPARENT SADNESS	2	2	2	1	1	1	0
					04.SUICIDAL THOUGHTS	1	1	1	0	1	0	0
					05.INERTIA	1	1	1	1	0	0	0
					06.INABILITY TO FEEL	1	2	1	1	1	0	0
					07.PESSIMISTIC THOUGHTS	1	0	0	0	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	0
					09.REDUCED SLEEP	2	3	3	2	2	2	3
					10.REDUCED APPETITE	2	1	1	1	2	1	1
					11.Total score	17	15	13	9	11	7	5
	153	Reboxetine	Male	1	01.REPORTED SADNESS	1	1	1	0	0	0	1
					02.INNER TENSION	2	2	1	1	1	1	1
					03.APPARENT SADNESS	1	1	1	1	1	1	1
					04.SUICIDAL THOUGHTS	1	1	1	1	0	0	0
					05.INERTIA	2	2	1	1	1	1	1
					06.INABILITY TO FEEL	2	2	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1
					09.REDUCED SLEEP	2	2	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	1	1	0	1
					11.Total score	15	15	10	9	7	7	8
	154	Imipramine	Female	1	01.REPORTED SADNESS	1						
					02.INNER TENSION	2						
					03.APPARENT SADNESS	1						
					04.SUICIDAL THOUGHTS	1						
					05.INERTIA	1						
					06.INABILITY TO FEEL	1						
					07.PESSIMISTIC THOUGHTS	1						
					08.CONCENTRATIONS DIFFICULTIES	1						
					09.REDUCED SLEEP	3						
					10.REDUCED APPETITE	2						
					11.Total score	14						
	155	Placebo	Male	1	01.REPORTED SADNESS	2	2	3	2	2	2	2
					02.INNER TENSION	2	2	2	2	2	2	2
					03.APPARENT SADNESS	2	2	2	2	2	2	2
					04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1
					05.INERTIA	1	1	2	2	2	2	2
					06.INABILITY TO FEEL	2	2	1	2	2	2	2
					07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2
					09.REDUCED SLEEP	2	2	2	2	2	2	2

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40

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/1	155	Placebo	Male	1	10. REDUCED APPETITE 11. Total score	2 19	2 19	1 18	1 18	2 20		
	156	Placebo	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 1 1 1 2 2 2 2 1 2 15	2 1 1 0 2 2 1 1 1 2 12	1 1 0 0 2 1 0 1 1 0 6	1 2 1 0 0 1 1 1 1 0 6	1 0 0 0 1 1 1 1 0 4	0 0 0 0 1 0 1 1 0 3	1 1 0 0 1 1 1 1 0 5
6/2	157	Reboxetine	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 2 2 2 3 2 2 1 19	2 1 2 2 2 2 2 2 2 2 17	2 1 0 1 1 1 2 2 2 0 13	1 1 2 1 1 0 2 2 2 10	1 1 2 2 1 1 2 2 1 10	1 1 2 2 1 1 2 2 0 9	1 1 2 2 1 1 2 2 0 9
	158	Imipramine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	3 2 2 0 2 2 3 2 2 2 19	3 2 2 0 2 2 3 2 2 2 19	2 2 2 0 2 2 2 2 2 1 16	1 2 2 0 2 1 2 2 2 1 13	1 2 2 0 2 1 2 2 2 0 10	1 1 2 0 1 0 1 1 0 0 5	1 1 2 0 1 0 1 1 0 0 5
159	Imipramine	Male	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES	2 2 1 1 2 2 2 2	2 2 1 1 2 2 2 2	3 1 2 2 2 2 2 2	3 1 2 2 2 2 2 2	2 1 1 2 2 2 2 2	2 1 1 2 2 2 2 2	3 1 1 2 2 2 2 2	

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
6/2	159	Imipramine	Male	1	09. REDUCED SLEEP	1	0	0	0	0	0	0					
					10. REDUCED APPETITE	1	1	2	2	0	0	1					
					11. Total score	16	15	17	16	10	10	14					
					160	Placebo	Male	1	04. REPORTED SADNESS	2	0	0	0	0	0	0	1
									02. INNER TENSION	2	0	0	0	0	0	0	1
									03. APPARENT SADNESS	3	0	0	0	0	0	0	1
									04. SUICIDAL THOUGHTS	2	0	0	0	0	0	0	1
									05. INERTIA	2	1	1	1	1	1	2	
									06. INABILITY TO FEEL	2	1	1	1	1	1	2	
									07. PESSIMISTIC THOUGHTS	2	1	1	1	1	1	2	
									08. CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	2	
09. REDUCED SLEEP	3	1	1	1					1	1	1						
10. REDUCED APPETITE	0	0	0	0					0	0	0						
11. Total score	19	5	5	5					5	5	13						
133	161	Reboxetine	Female	1	04. REPORTED SADNESS	2	2	2	1	1	1	1					
					02. INNER TENSION	2	2	2	2	2	2	2					
					03. APPARENT SADNESS	2	2	1	1	1	1	1					
					04. SUICIDAL THOUGHTS	2	2	1	1	1	1	1					
					05. INERTIA	2	2	1	1	1	1	1					
					06. INABILITY TO FEEL	2	2	1	1	1	1	1					
					07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1					
					08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1					
					09. REDUCED SLEEP	1	1	1	1	1	1	1					
					10. REDUCED APPETITE	1	1	1	1	1	1	1					
					11. Total score	17	17	11	11	11	11	11					
50	162	Placebo	Male	1	01. REPORTED SADNESS	2	2	2	2	2	2	2					
					02. INNER TENSION	2	2	2	2	2	2	2					
					03. APPARENT SADNESS	2	2	2	2	2	2	2					
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1					
					05. INERTIA	1	1	1	1	1	1	1					
					06. INABILITY TO FEEL	2	2	2	2	2	2	2					
					07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2					
					08. CONCENTRATIONS DIFFICULTIES	3	3	3	3	3	3	3					
					09. REDUCED SLEEP	1	1	1	1	1	1	1					
					10. REDUCED APPETITE	2	2	2	2	2	2	2					
					11. Total score	18	18	16	16	16	16	16					
169	169	Imipramine	Female	1	01. REPORTED SADNESS	3	0	3	3	3	3	3					
					02. INNER TENSION	2	1	3	3	3	3	3					
					03. APPARENT SADNESS	3	0	3	3	3	3	3					
					04. SUICIDAL THOUGHTS	2	0	2	2	2	2	2					
					05. INERTIA	3	0	3	3	3	3	3					
					06. INABILITY TO FEEL	3	0	3	3	3	3	3					
					07. PESSIMISTIC THOUGHTS	2	0	2	2	2	2	2					

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43

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
6/2	173	Placobo	Male	1	07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 0 20	2 2 2 0 19	2 2 2 0 19	2 2 2 1 20	2 3 2 1 24	1 1 1 0 12	1 1 1 0 14	
174		Reboxetine	Male	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	3 1 3 3 3 2 3 2 2 0 25	0 0 0 0 0 0 0 0 0 0 3	0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0	2 1 2 0 1 1 0 0 0 0 10	
6/3	163	Reboxetine	Male	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 1 1 1 1 2 0 0 12	2 2 2 1 1 1 1 2 0 0 12	2 2 2 1 1 1 1 2 0 0 12	2 2 2 1 1 1 1 2 0 0 12	2 2 2 1 1 1 1 2 0 0 12	2 2 2 1 1 1 1 2 0 0 12	1 1 1 0 0 0 0 2 0 0 12	
164		Imipramine	Male	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 0 2 2 1 1 0 1 13	2 2 2 0 2 2 1 1 0 0 13	2 2 2 0 2 2 1 1 0 0 11	2 2 2 0 2 2 1 1 0 0 12	2 2 2 0 2 2 1 1 0 0 11	2 2 2 0 2 2 1 1 0 0 9	1 1 1 0 0 0 0 2 0 0 6	
165		Imipramine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA	2 2 2 0 2	2 2 2 0 2	2 2 2 0 2	2 2 2 0 2	2 2 2 0 2	2 2 2 0 2	2 2 2 0 2	1 1 1 0 2

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	165	Imipramine	Female	1	06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 1 2 2 1 16	2 1 1 1 0 13	2 1 1 1 0 12	2 1 1 1 0 13	1 1 2 0 0 8	1 1 2 0 0 9	1 1 2 0 0 8
	166	Reboxetine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 0 2 2 1 2 1 1 15	2 2 2 0 1 2 2 1 1 1 19	2 2 2 0 1 2 2 1 1 1 19	2 2 2 0 1 2 2 1 1 1 19	2 2 2 0 1 2 2 1 1 1 19	2 2 2 0 1 2 2 1 1 1 19	2 2 2 0 1 2 2 1 1 1 19
	167	Placebo	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 2 0 1 1 2 1 2 0 11	2 2 2 0 1 1 1 1 1 0 11	2 2 2 0 1 1 1 1 1 0 11	2 2 2 0 1 1 1 1 1 0 11	2 2 2 0 1 1 1 1 1 0 11	2 2 2 0 1 1 1 1 1 0 11	2 2 2 0 1 1 1 1 1 0 11
	168	Placebo	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	3 2 3 0 2 2 0 3 2 2 20	3 2 3 0 2 2 0 3 2 2 20	3 2 3 0 2 2 0 3 2 2 20	3 2 3 0 2 2 0 3 2 2 20	3 2 3 0 2 2 0 3 2 2 20	3 2 3 0 2 2 0 3 2 2 20	
	505	Imipramine	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS	2 2 2 0	2 2 2 0	2 2 2 0	2 2 2 0	2 2 2 0	2 2 2 0	2 2 2 0

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45

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PHARMACIA CVS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	505	Imipramine	Female	1	05. INERTIA	1	2	1				
					06. INABILITY TO FEEL	2	2	1				
					07. PESSIMISTIC THOUGHTS	2	2	1				
					08. CONCENTRATIONS DIFFICULTIES	2	2	1				
					09. REDUCED SLEEP	0	2	3				
					10. REDUCED APPETITE	0	1	1				
					11. Total score	13	17	14				
					01. REPORTED SADNESS	2	2	2	2	2	1	2
					02. INNER TENSION	3	2	2	2	2	1	2
					03. APPARENT SADNESS	2	2	2	2	1	1	1
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
05. INERTIA	2	2	2	1	2	1	1					
06. INABILITY TO FEEL	1	1	1	2	1	1	1					
07. PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1					
08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2					
09. REDUCED SLEEP	2	2	2	2	2	2	2					
10. REDUCED APPETITE	1	0	0	0	0	0	0					
11. Total score	17	15	16	13	11	11	11					
507	507	Imipramine	Female	1	01. REPORTED SADNESS	2	2	1	1	1	1	1
					02. INNER TENSION	2	2	2	1	0	1	0
					03. APPARENT SADNESS	1	1	2	1	1	1	0
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					05. INERTIA	1	1	1	1	1	1	0
					06. INABILITY TO FEEL	2	1	1	1	1	1	0
					07. PESSIMISTIC THOUGHTS	2	1	2	2	2	2	1
					08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	0	1	0
					09. REDUCED SLEEP	0	1	0	0	0	0	0
					10. REDUCED APPETITE	0	0	0	0	0	0	0
					11. Total score	12	11	10	8	7	4	2
508	508	Reboxetine	Female	1	01. REPORTED SADNESS	2	1	1	1	2	1	0
					02. INNER TENSION	2	1	1	1	1	1	1
					03. APPARENT SADNESS	1	1	1	1	2	1	1
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					05. INERTIA	2	1	1	1	1	1	1
					06. INABILITY TO FEEL	1	1	1	1	1	1	0
					07. PESSIMISTIC THOUGHTS	2	1	2	1	1	1	0
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	0
					09. REDUCED SLEEP	0	1	0	1	0	1	1
					10. REDUCED APPETITE	0	0	0	0	0	0	0
					11. Total score	12	9	9	8	10	8	5
509	509	Placebo	Male	1	01. REPORTED SADNESS	2	1	1	1	1	1	1
					02. INNER TENSION	2	1	1	2	1	1	1
					03. APPARENT SADNESS	1	1	2	1	1	1	1

1354

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46

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	509	Placebo	Male	1	04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	0 1 2 1 1 1 1 13	0 0 1 1 1 1 0 8	0 0 1 1 1 1 0 9	0 1 1 1 2 2 1 11	0 1 1 1 2 2 1 8	0 1 1 1 2 2 0 9	0 1 1 1 2 2 0 8
510	Reboxetine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 2 2 2 2 2 2 0 14	2 1 1 0 1 1 1 11	2 2 2 0 1 1 1 8	2 2 2 0 1 1 1 12	2 1 1 0 1 1 2 12	2 1 1 1 1 1 2 12	2 1 1 1 1 1 2 12	2 1 1 1 2 2 0 12
511	Imipramine	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 0 1 1 1 2 2 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	
512	Placebo	Female	1	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 2 0 1 1 1 2 2 0 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	2 2 2 0 1 1 1 13	
513	Imipramine	Female	1	01.REPORTED SADNESS 02.INNER TENSION	2 2	2 2	2 2	2 2	2 2	2 2	2 2	2 2

13
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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	513	Imipramine	Female	1	03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 0 1 1 1 2 2 0 13	1 0 1 1 1 1 2 0 10	1 0 1 1 1 0 1 0 7	1 0 0 1 1 2 1 0 8	1 0 0 1 1 1 1 0 7	1 0 0 1 1 1 1 0 5	1 0 0 1 1 1 1 0 5
7/02	181	Reboxetine	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL 09. PESSIMISTIC THOUGHTS 10. SUICIDAL THOUGHTS 11. Total score	3 3 3 3 1 2 2 3 3 1 24	3 3 3 3 1 2 2 3 3 1 24	3 3 3 3 2 2 2 3 3 1 24	3 3 3 3 1 2 2 3 3 1 22	3 3 3 3 2 2 2 3 3 1 20	3 2 3 3 1 2 2 3 3 1 18	2 2 1 1 0 2 2 2 2 1 16
182		Placebo	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL 09. PESSIMISTIC THOUGHTS 10. SUICIDAL THOUGHTS 11. Total score	4 4 4 2 3 3 3 2 2 1 28	4 5 4 2 3 3 3 3 2 2 34	4 4 3 2 2 2 3 3 2 2 26	4 3 3 3 2 2 3 3 2 2 24	3 3 3 3 3 2 2 3 3 1 23	3 3 3 3 3 2 2 3 3 1 24	
183		Imipramine	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL 09. PESSIMISTIC THOUGHTS 10. SUICIDAL THOUGHTS 11. Total score	3 3 3 5 5 2 4 3 2 1 32	3 4 4 6 6 2 4 3 3 1 35	3 3 4 6 5 2 4 3 3 1 35	3 5 5 6 5 4 4 4 3 1 42	5 5 4 6 5 4 5 4 3 1 42	5 4 4 6 5 4 5 4 3 1 42	
184		Imipramine	Female	2	01. APPARENT SADNESS	4	4	3	2	2	1	1

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48

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/02	184	Imipramine	Female	2	02. REPORTED SADNESS	4	4	3	2	2	1	1
					03. INNER TENSION	4	4	3	2	2	1	0
					04. REDUCED SLEEP	4	4	4	2	2	1	0
					05. REDUCED APPETITE	2	2	1	0	0	0	0
					06. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	0	0
					07. LASSITUDE	4	4	4	2	2	0	0
					08. INABILITY TO FEEL	4	4	2	2	2	1	1
					09. PESSIMISTIC THOUGHTS	2	2	2	2	2	1	0
					10. SUICIDAL THOUGHTS	1	1	1	1	1	0	0
					11. Total score	31	31	22	16	16	6	3
						185	Reboxetine	Male	2	01. APPARENT SADNESS	2	3
02. REPORTED SADNESS	2	2	3	1						3	3	3
03. INNER TENSION	2	2	2	2						2	2	2
04. REDUCED SLEEP	5	5	5	4						5	5	5
05. REDUCED APPETITE	2	2	2	2						2	2	2
06. CONCENTRATIONS DIFFICULTIES	1	1	1	1						1	1	1
07. LASSITUDE	0	1	1	1						1	1	1
08. INABILITY TO FEEL	1	1	2	1						2	1	2
09. PESSIMISTIC THOUGHTS	4	4	3	4						2	2	2
10. SUICIDAL THOUGHTS	1	1	1	1						1	1	1
11. Total score	20	22	24	21						22	17	14
	186	Placebo	Male	2	01. APPARENT SADNESS	2	1	2	1	1	1	0
					02. REPORTED SADNESS	3	2	2	2	1	1	1
					03. INNER TENSION	4	3	2	2	1	1	1
					04. REDUCED SLEEP	5	5	5	4	4	3	1
					05. REDUCED APPETITE	1	1	1	1	1	1	0
					06. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
					07. LASSITUDE	1	1	1	1	1	1	1
					08. INABILITY TO FEEL	2	2	2	2	2	1	0
					09. PESSIMISTIC THOUGHTS	2	2	2	2	2	1	0
					10. SUICIDAL THOUGHTS	2	2	1	1	1	1	0
					11. Total score	23	20	19	17	14	12	5
	535	Placebo	Male	2	01. APPARENT SADNESS	2	2	2	2	2	2	1
					02. REPORTED SADNESS	1	1	1	1	1	1	1
					03. INNER TENSION	3	3	3	3	3	3	2
					04. REDUCED SLEEP	1	1	1	1	1	1	1
					05. REDUCED APPETITE	1	1	1	1	1	1	0
					06. CONCENTRATIONS DIFFICULTIES	3	3	3	2	2	2	2
					07. LASSITUDE	3	3	3	3	3	2	2
					08. INABILITY TO FEEL	5	5	5	3	3	2	2
					09. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2
					10. SUICIDAL THOUGHTS	2	2	1	1	1	1	1
					11. Total score	20	20	20	16	17	17	14

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49

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/02	536	Reboxetine	Female	2	01. APPARENT SADNESS	3	3	2	2	1	1	1
					02. REPORTED SADNESS	3	2	2	2	2	1	1
					03. INNER TENSION	2	2	2	2	1	1	1
					04. REDUCED SLEEP	4	4	3	3	1	1	1
					05. REDUCED APPETITE	0	0	0	0	0	1	1
					06. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1
					07. LASSITUDE	4	4	3	2	1	1	1
					08. INABILITY TO FEEL	3	3	2	2	1	1	1
					09. PESSIMISTIC THOUGHTS	2	2	2	2	2	1	1
					10. SUICIDAL THOUGHTS	1	1	1	1	1	1	1
					11. Total score	24	24	18	17	11	10	10
7/03	187	Imipramine	Female	2	01. APPARENT SADNESS	4	4	4	4	4	2	2
					02. REPORTED SADNESS	3	3	3	3	3	2	2
					03. INNER TENSION	1	1	1	1	1	0	0
					04. REDUCED SLEEP	4	4	4	4	4	1	1
					05. REDUCED APPETITE	1	1	1	1	1	0	0
					06. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	2	2
					07. LASSITUDE	2	2	2	2	2	2	2
					08. INABILITY TO FEEL	2	3	3	3	3	3	3
					09. PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1
					10. SUICIDAL THOUGHTS	1	0	0	0	0	0	0
					11. Total score	21	23	23	23	23	13	13
188	188	Placebo	Male	2	01. APPARENT SADNESS	4	4	4	4	2	2	1
					02. REPORTED SADNESS	4	4	4	4	2	2	1
					03. INNER TENSION	2	2	2	2	1	1	1
					04. REDUCED SLEEP	4	4	4	4	2	2	1
					05. REDUCED APPETITE	2	2	2	2	1	1	0
					06. CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	0
					07. LASSITUDE	2	2	2	2	2	2	1
					08. INABILITY TO FEEL	2	2	2	2	1	1	1
					09. PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1
					10. SUICIDAL THOUGHTS	2	2	2	2	0	0	0
					11. Total score	26	26	26	26	13	7	7
189	189	Placebo	Male	2	01. APPARENT SADNESS	4	4	4	4	0	0	0
					02. REPORTED SADNESS	4	4	4	4	1	1	1
					03. INNER TENSION	2	2	2	2	0	0	0
					04. REDUCED SLEEP	4	4	4	4	0	0	0
					05. REDUCED APPETITE	2	2	2	2	0	0	0
					06. CONCENTRATIONS DIFFICULTIES	4	4	4	4	1	1	1
					07. LASSITUDE	1	1	1	1	1	1	1
					08. INABILITY TO FEEL	2	2	2	2	0	0	0
					09. PESSIMISTIC THOUGHTS	1	1	1	1	0	0	0
					10. SUICIDAL THOUGHTS	1	1	1	1	0	0	0
					11. Total score	25	25	25	25	3	4	4

13
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50

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	190	Reboxetine	Male	2	01. APPARENT SADNESS	4	4	4	2	2	2	2
					02. REPORTED SADNESS	3	3	3	1	1	1	1
					03. INNER TENSION	2	2	2	1	1	1	1
					04. REDUCED SLEEP	3	3	3	1	1	1	1
					05. REDUCED APPETITE	1	1	1	0	0	0	0
					06. CONCENTRATIONS DIFFICULTIES	2	4	4	2	2	2	2
					07. LASSITUDE	2	3	3	1	1	1	1
					08. INABILITY TO FEEL	2	2	2	2	2	2	2
					09. PESSIMISTIC THOUGHTS	1	3	3	1	1	1	1
					10. SUICIDAL THOUGHTS	0	1	1	0	0	0	0
					11. Total score	20	26	26	11	11	11	11
13	191	Imipramine	Female	2	01. APPARENT SADNESS	4	3	3	2	2	2	2
13					02. REPORTED SADNESS	4	2	2	1	1	1	1
13					03. INNER TENSION	3	1	1	1	1	1	1
13					04. REDUCED SLEEP	3	1	1	1	1	1	1
13					05. REDUCED APPETITE	1	1	1	0	0	0	0
13					06. CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1
13					07. LASSITUDE	3	2	2	1	1	1	1
13					08. INABILITY TO FEEL	4	3	3	2	2	2	2
13					09. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	1
13					10. SUICIDAL THOUGHTS	1	1	1	1	1	1	1
13					11. Total score	27	17	17	11	11	11	11
13	192	Reboxetine	Female	2	01. APPARENT SADNESS	3	3	2	3	3	3	3
13					02. REPORTED SADNESS	3	3	1	2	2	2	2
13					03. INNER TENSION	1	1	1	1	1	1	1
13					04. REDUCED SLEEP	2	2	1	2	2	2	2
13					05. REDUCED APPETITE	2	2	0	2	2	2	2
13					06. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2
13					07. LASSITUDE	2	2	2	2	2	2	2
13					08. INABILITY TO FEEL	2	2	1	2	2	2	2
13					09. PESSIMISTIC THOUGHTS	2	2	1	2	2	2	2
13					10. SUICIDAL THOUGHTS	1	1	1	1	1	1	1
13					11. Total score	20	20	12	19	19	19	19
13	523	Reboxetine	Female	2	01. APPARENT SADNESS	4	4	4	2	2	2	2
13					02. REPORTED SADNESS	4	4	4	2	2	2	2
13					03. INNER TENSION	2	2	2	1	1	1	1
13					04. REDUCED SLEEP	4	4	4	1	1	1	1
13					05. REDUCED APPETITE	2	2	2	0	0	0	0
13					06. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1
13					07. LASSITUDE	4	4	4	1	1	1	1
13					08. INABILITY TO FEEL	4	4	4	2	2	2	2
13					09. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2
13					10. SUICIDAL THOUGHTS	2	2	2	0	0	0	0

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51

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	523	Reboxetine	Female	2	30	30	30	12	12	12	12
					11.Total score						
	524	Placebo	Female	2	4	4	4	2	1	1	1
					01.APPARENT SADNESS						
					02.REPORTED SADNESS						
					03.INNER TENSION						
					04.REDUCED SLEEP						
					05.REDUCED APPETITE						
					06.CONCENTRATIONS DIFFICULTIES						
					07.LASSITUDE						
					08.INABILITY TO FEEL						
					09.PESSIMISTIC THOUGHTS						
					10.SUICIDAL THOUGHTS						
					11.Total score						
	525	Placebo	Female	2	4	4	3	2	2	1	1
					01.APPARENT SADNESS						
					02.REPORTED SADNESS						
					03.INNER TENSION						
					04.REDUCED SLEEP						
					05.REDUCED APPETITE						
					06.CONCENTRATIONS DIFFICULTIES						
					07.LASSITUDE						
					08.INABILITY TO FEEL						
					09.PESSIMISTIC THOUGHTS						
					10.SUICIDAL THOUGHTS						
					11.Total score						
	526	Reboxetine	Female	2	4	4	3	3	3	2	1
					01.APPARENT SADNESS						
					02.REPORTED SADNESS						
					03.INNER TENSION						
					04.REDUCED SLEEP						
					05.REDUCED APPETITE						
					06.CONCENTRATIONS DIFFICULTIES						
					07.LASSITUDE						
					08.INABILITY TO FEEL						
					09.PESSIMISTIC THOUGHTS						
					10.SUICIDAL THOUGHTS						
					11.Total score						
	527	Imipramine	Female	2	4	4	4	2	2	2	2
					01.APPARENT SADNESS						
					02.REPORTED SADNESS						
					03.INNER TENSION						
					04.REDUCED SLEEP						
					05.REDUCED APPETITE						
					06.CONCENTRATIONS DIFFICULTIES						
					07.LASSITUDE						
					08.INABILITY TO FEEL						
					09.PESSIMISTIC THOUGHTS						

1360

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52

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	527	Imipramine	Female	2	22	22	22	13	13	0	0
					10. SUICIDAL THOUGHTS						
					11. Total score						
	528	Imipramine	Female	2	3	3	3	3	3	3	3
					01. APPARENT SADNESS						
					02. REPORTED SADNESS						
					03. INNER TENSION						
					04. REDUCED SLEEP						
					05. REDUCED APPETITE						
					06. CONCENTRATIONS DIFFICULTIES						
					07. LASSITUDE						
					08. INABILITY TO FEEL						
					09. PESSIMISTIC THOUGHTS						
					10. SUICIDAL THOUGHTS						
					11. Total score						
7/04	193	Placebo	Female	2	5	4	4	3	2	1	1
					01. APPARENT SADNESS						
					02. REPORTED SADNESS						
					03. INNER TENSION						
					04. REDUCED SLEEP						
					05. REDUCED APPETITE						
					06. CONCENTRATIONS DIFFICULTIES						
					07. LASSITUDE						
					08. INABILITY TO FEEL						
					09. PESSIMISTIC THOUGHTS						
					10. SUICIDAL THOUGHTS						
					11. Total score						
194		Reboxetine	Male	2	5	5	4	3	2	1	1
					01. APPARENT SADNESS						
					02. REPORTED SADNESS						
					03. INNER TENSION						
					04. REDUCED SLEEP						
					05. REDUCED APPETITE						
					06. CONCENTRATIONS DIFFICULTIES						
					07. LASSITUDE						
					08. INABILITY TO FEEL						
					09. PESSIMISTIC THOUGHTS						
					10. SUICIDAL THOUGHTS						
					11. Total score						
195		Placebo	Female	2	6	6	6	4	2	1	1
					01. APPARENT SADNESS						
					02. REPORTED SADNESS						
					03. INNER TENSION						
					04. REDUCED SLEEP						
					05. REDUCED APPETITE						
					06. CONCENTRATIONS DIFFICULTIES						
					07. LASSITUDE						
					08. INABILITY TO FEEL						

1361

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53

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
7/04	195	Placobo	Female	2	09. PESSIMISTIC THOUGHTS	4	4	4	3	1	1	1					
					10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0					
					11. Total score	41	41	29	14	8	5						
					196	Reboxetine	Female	2	01. APPARENT SADNESS	4	4	4	3	2	2	1	0
									02. REPORTED SADNESS	4	4	4	3	3	2	1	
									03. INNER TENSION	4	4	4	3	3	2	1	
									04. REDUCED SLEEP	4	4	4	3	2	2	1	
									05. REDUCED APPETITE	4	4	4	3	2	2	1	
									06. CONCENTRATIONS DIFFICULTIES	4	4	4	3	2	2	1	
									07. LASSITUDE	3	3	3	3	2	2	1	
					08. INABILITY TO FEEL	4	4	4	2	2	2	1					
09. PESSIMISTIC THOUGHTS	4	4	4	3	2	2	1										
10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0										
11. Total score	35	35	35	27	22	15	7										
1362	197	Imipramine	Male	2	01. APPARENT SADNESS	4	4	4	4	4	4	4					
					02. REPORTED SADNESS	4	4	4	4	4	4	4					
					03. INNER TENSION	4	4	4	4	4	4	4					
					04. REDUCED SLEEP	4	4	4	4	4	4	4					
					05. REDUCED APPETITE	5	5	5	5	5	5	5					
					06. CONCENTRATIONS DIFFICULTIES	4	4	4	4	4	4	4					
					07. LASSITUDE	4	4	4	4	4	4	4					
					08. INABILITY TO FEEL	4	4	4	4	4	4	4					
					09. PESSIMISTIC THOUGHTS	4	4	4	4	4	4	4					
					10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0					
					11. Total score	37	37	37	37	37	37	37					
1362	198	Imipramine	Female	2	01. APPARENT SADNESS	4	4	4	4	2	4	2					
					02. REPORTED SADNESS	4	4	4	4	4	2	2					
					03. INNER TENSION	6	6	4	4	2	4	2					
					04. REDUCED SLEEP	4	4	2	2	2	2	2					
					05. REDUCED APPETITE	4	4	4	2	2	2	2					
					06. CONCENTRATIONS DIFFICULTIES	4	4	4	2	2	2	2					
					07. LASSITUDE	4	4	4	2	2	2	2					
					08. INABILITY TO FEEL	2	2	2	2	2	2	2					
					09. PESSIMISTIC THOUGHTS	4	4	4	4	2	2	2					
					10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0					
					11. Total score	36	36	32	26	20	22	18					
1362	199	Imipramine	Male	2	01. APPARENT SADNESS	4	4	4	4	3	3	3					
					02. REPORTED SADNESS	4	4	4	4	3	2	2					
					03. INNER TENSION	3	4	4	4	2	2	2					
					04. REDUCED SLEEP	4	4	4	4	2	2	2					
					05. REDUCED APPETITE	4	4	4	4	2	1	1					
					06. CONCENTRATIONS DIFFICULTIES	5	5	5	4	4	4	4					
					07. LASSITUDE	4	4	4	4	2	2	1					

9550082

54

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PHARMACIA CMS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
7/04	199	Imipramine	Male	2	08. INABILITY TO FEEL	4	4	4	3	3	2	1					
					09. PESSIMISTIC THOUGHTS	4	4	4	4	2	2	2					
					10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0					
					11. Total score	36	37	37	35	23	20	18					
					200	Placebo	Male	2	01. APPARENT SADNESS	4	4	3	3	3	3	3	2
									02. REPORTED SADNESS	3	3	3	3	2	2	2	
									03. INNER TENSION	3	4	4	4	2	2	2	
									04. REDUCED SLEEP	4	4	4	4	2	2	1	
									05. REDUCED APPETITE	4	4	4	3	2	2	2	
									06. CONCENTRATIONS DIFFICULTIES	4	5	4	5	4	4	4	
									07. LASSITUDE	4	4	4	4	2	2	2	
08. INABILITY TO FEEL	4	4	4	3					2	2	2						
09. PESSIMISTIC THOUGHTS	4	4	4	4					2	2	2						
10. SUICIDAL THOUGHTS	0	0	0	0					0	0	0						
11. Total score	34	36	34	33					21	21	19						
201	Reboxetine	Female	2	01. APPARENT SADNESS	4	4	3	1	2	1	1	1					
				02. REPORTED SADNESS	3	3	3	2	2	1	1						
				03. INNER TENSION	3	4	3	2	2	1	1						
				04. REDUCED SLEEP	4	4	4	2	2	1	1						
				05. REDUCED APPETITE	4	4	4	2	2	1	1						
				06. CONCENTRATIONS DIFFICULTIES	4	4	4	3	3	4	4						
				07. LASSITUDE	3	4	3	2	2	1	1						
				08. INABILITY TO FEEL	4	4	4	1	2	1	1						
				09. PESSIMISTIC THOUGHTS	4	4	4	2	2	1	1						
				10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0						
				11. Total score	33	35	32	17	19	12	12						
202	Reboxetine	Male	2	01. APPARENT SADNESS	4	4	3	3	3	2	2	2					
				02. REPORTED SADNESS	4	4	4	4	3	2	2						
				03. INNER TENSION	5	5	4	4	3	2	2						
				04. REDUCED SLEEP	5	4	4	4	4	3	2						
				05. REDUCED APPETITE	2	2	2	2	2	2	2						
				06. CONCENTRATIONS DIFFICULTIES	6	6	6	6	5	5	5						
				07. LASSITUDE	4	4	4	4	4	4	4						
				08. INABILITY TO FEEL	5	5	5	4	4	3	2						
				09. PESSIMISTIC THOUGHTS	3	3	3	3	3	2	2						
				10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0						
				11. Total score	38	37	35	34	31	25	23						
203	Placebo	Female	2	01. APPARENT SADNESS	5	5	5	4	5	5	3	3					
				02. REPORTED SADNESS	5	5	5	5	4	3	3						
				03. INNER TENSION	5	5	5	5	4	3	2						
				04. REDUCED SLEEP	5	5	5	5	4	4	3						
				05. REDUCED APPETITE	5	5	5	5	5	3	3						
				06. CONCENTRATIONS DIFFICULTIES	5	5	5	5	5	4	4						

1363

9550082

55

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PHARMACIA CNS R&D
 REMOETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/04	203	Placebo	Female	2	07. LASSITUDE	4	4	4	4	3	3	3
					08. INABILITY TO FEEL	4	4	4	3	3	3	2
					09. PESSIMISTIC THOUGHTS	4	4	4	4	4	4	3
					10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					11. Total score	42	42	42	39	31	27	26
204		Imipramine	Female	2	01. APPARENT SADNESS	5	5	5	4	4	3	3
					02. REPORTED SADNESS	4	4	4	4	3	3	3
					03. INNER TENSION	5	5	4	3	2	2	2
					04. REDUCED SLEEP	5	5	2	1	1	1	1
					05. REDUCED APPETITE	2	2	1	1	1	0	0
					06. CONCENTRATIONS DIFFICULTIES	5	5	5	5	5	5	4
					07. LASSITUDE	5	5	4	3	3	3	3
					08. INABILITY TO FEEL	4	4	3	2	3	2	2
					09. PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1
					10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					11. Total score	37	37	30	24	23	21	19
7/05	205	Placebo	Male	2	01. APPARENT SADNESS	4	4	4	4	4	4	4
					02. REPORTED SADNESS	3	3	3	3	3	3	3
					03. INNER TENSION	4	4	4	4	4	4	4
					04. REDUCED SLEEP	4	4	4	4	4	4	4
					05. REDUCED APPETITE	2	3	3	3	3	3	3
					06. CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	2	2
					07. LASSITUDE	3	3	3	3	3	3	3
					08. INABILITY TO FEEL	3	3	4	4	4	4	4
					09. PESSIMISTIC THOUGHTS	4	4	4	4	4	4	4
					10. SUICIDAL THOUGHTS	1	1	1	1	1	1	1
					11. Total score	31	32	31	31	31	31	31
206		Imipramine	Female	2	01. APPARENT SADNESS	4	3	3	2	2	2	2
					02. REPORTED SADNESS	3	3	3	2	2	1	1
					03. INNER TENSION	3	3	3	2	2	1	1
					04. REDUCED SLEEP	4	3	2	2	2	2	2
					05. REDUCED APPETITE	3	2	2	1	1	1	1
					06. CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	2	2
					07. LASSITUDE	4	3	2	2	2	2	2
					08. INABILITY TO FEEL	3	3	3	2	2	2	2
					09. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	1
					10. SUICIDAL THOUGHTS	1	1	1	1	1	0	0
					11. Total score	30	26	23	17	17	14	14
207		Imipramine	Female	2	01. APPARENT SADNESS	3	3	3	2	2	2	2
					02. REPORTED SADNESS	3	3	2	2	2	2	2
					03. INNER TENSION	3	3	3	3	2	2	2
					04. REDUCED SLEEP	3	2	2	2	2	1	1
					05. REDUCED APPETITE	2	1	1	1	1	1	1

1364

9550082

56

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/05	207	Imipramine	Female	2	06.CONCENTRATIONS DIFFICULTIES 07.LASSITUDE 08.INABILITY TO FEEL 09.PESSIMISTIC THOUGHTS 10.SUICIDAL THOUGHTS 11.Total score	2	2	2	2	1	1	1
208		Reboxetine	Male	2	01.APPARENT SADNESS 02.REPORTED SADNESS 03.INNER TENSION 04.REDUCED SLEEP 05.REDUCED APPETITE 06.CONCENTRATIONS DIFFICULTIES 07.LASSITUDE 08.INABILITY TO FEEL 09.PESSIMISTIC THOUGHTS 10.SUICIDAL THOUGHTS 11.Total score	3	3	3	2	2	1	1
209		Placebo	Male	2	01.APPARENT SADNESS 02.REPORTED SADNESS 03.INNER TENSION 04.REDUCED SLEEP 05.REDUCED APPETITE 06.CONCENTRATIONS DIFFICULTIES 07.LASSITUDE 08.INABILITY TO FEEL 09.PESSIMISTIC THOUGHTS 10.SUICIDAL THOUGHTS 11.Total score	3	3	3	3	3	3	3
210		Reboxetine	Male	2	01.APPARENT SADNESS 02.REPORTED SADNESS 03.INNER TENSION 04.REDUCED SLEEP 05.REDUCED APPETITE 06.CONCENTRATIONS DIFFICULTIES 07.LASSITUDE 08.INABILITY TO FEEL 09.PESSIMISTIC THOUGHTS 10.SUICIDAL THOUGHTS 11.Total score	3	2	2	2	1	1	1
541		Reboxetine	Female	2	01.APPARENT SADNESS 02.REPORTED SADNESS 03.INNER TENSION 04.REDUCED SLEEP	4	3	2	1	1	1	1

1365

9550082

57

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CMS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
7/05	541	Reboxetine	Female	2	05. REDUCED APETITE	2	2	0	0	0	0	0	0				
					06. CONCENTRATIONS DIFFICULTIES	4	3	2	1	1	1	1					
					07. LASSITUDE	4	3	2	2	1	1	1					
					08. INABILITY TO FEEL	4	3	2	1	1	1	1					
					09. PESSIMISTIC THOUGHTS	3	2	1	1	0	0	0					
					10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0					
					11. Total score	31	24	14	7	5	5	5					
					542	Imipramine	Male	2	01. APPARENT SADNESS	4	4	4	3	3	3	3	2
									02. REPORTED SADNESS	4	4	3	3	3	3	2	
									03. INNER TENSION	4	4	3	3	2	2	1	
									04. REDUCED SLEEP	4	4	3	3	2	2	2	
05. REDUCED APETITE	1	1	0	0					0	0	0						
06. CONCENTRATIONS DIFFICULTIES	4	4	4	3					2	2	2						
07. LASSITUDE	4	4	4	3					2	2	2						
08. INABILITY TO FEEL	4	4	3	3					2	2	2						
09. PESSIMISTIC THOUGHTS	4	4	3	2					1	1	1						
10. SUICIDAL THOUGHTS	0	0	0	0					0	0	0						
11. Total score	33	33	27	22					17	17	14						
543	Imipramine	Male	2	01. APPARENT SADNESS	4	4	2	2	2	2	2	1					
				02. REPORTED SADNESS	4	3	2	2	2	2	1						
				03. INNER TENSION	5	4	3	2	2	2	2						
				04. REDUCED SLEEP	5	4	3	2	1	1	1						
				05. REDUCED APETITE	0	0	0	0	0	0	0						
				06. CONCENTRATIONS DIFFICULTIES	3	3	3	2	2	1	1						
				07. LASSITUDE	4	3	3	3	2	1	1						
				08. INABILITY TO FEEL	3	3	2	2	1	1	1						
				09. PESSIMISTIC THOUGHTS	4	3	2	2	2	1	1						
				10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0						
				11. Total score	30	26	20	17	13	10	8						
544	Placebo	Female	2	01. APPARENT SADNESS	4	4	4	4	4	4	4	4					
				02. REPORTED SADNESS	4	4	4	4	4	4	4						
				03. INNER TENSION	3	3	3	3	3	3	3						
				04. REDUCED SLEEP	4	4	4	4	4	4	4						
				05. REDUCED APETITE	4	3	3	2	3	3	3						
				06. CONCENTRATIONS DIFFICULTIES	3	3	3	3	3	3	3						
				07. LASSITUDE	4	4	4	4	4	4	4						
				08. INABILITY TO FEEL	4	4	4	4	4	4	4						
				09. PESSIMISTIC THOUGHTS	2	3	3	3	3	3	3						
				10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0						
				11. Total score	32	32	32	31	32	32	32						
545	Placebo	Male	2	01. APPARENT SADNESS	4	4	4	4	4	4	4	4					
				02. REPORTED SADNESS	4	4	4	4	4	4	4						
				03. INNER TENSION	3	3	4	3	3	3	3						

1366

9550082

58

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
7/05	545	Placebo	Male	2	04. REDUCED SLEEP	5	5	4	5	5	5	5	5				
					05. REDUCED APPETITE	0	0	0	0	0	0	0	0				
					06. CONCENTRATIONS DIFFICULTIES	4	4	4	4	4	4	4					
					07. LASSITUDE	5	5	5	5	5	5	5					
					08. INABILITY TO FEEL	4	4	4	4	4	4	4					
					09. PESSIMISTIC THOUGHTS	3	3	3	3	3	3	3					
					10. SUICIDAL THOUGHTS	0	0	0	0	0	0	0					
					11. Total score	32	32	32	32	32	32	32	31				
					546	Reboxetine	Female	2	01. APPARENT SADNESS	4	4	3	2	2	1	1	1
									02. REPORTED SADNESS	4	3	3	2	1	1	1	
									03. INNER TENSION	3	3	2	2	1	1	0	
04. REDUCED SLEEP	3	3	2	2					1	1	1						
05. REDUCED APPETITE	0	0	0	0					0	0	0						
06. CONCENTRATIONS DIFFICULTIES	4	3	2	1					1	1	1						
07. LASSITUDE	3	3	2	2					2	2	1						
08. INABILITY TO FEEL	3	3	2	2					2	2	1						
09. PESSIMISTIC THOUGHTS	2	2	1	1					1	1	0						
10. SUICIDAL THOUGHTS	0	0	0	0					0	0	0						
11. Total score	26	24	17	13					10	10	6						
7/07	529	Placebo	Female	2	01. APPARENT SADNESS	4	4	4	3	4	4	3					
					02. REPORTED SADNESS	3	3	2	2	2	2	2					
					03. INNER TENSION	3	2	2	2	2	2	2					
					04. REDUCED SLEEP	4	4	3	3	3	2	2					
					05. REDUCED APPETITE	2	2	2	2	1	1	1					
					06. CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	2	2					
					07. LASSITUDE	3	3	2	2	2	1	2					
					08. INABILITY TO FEEL	2	2	3	2	2	2	2					
					09. PESSIMISTIC THOUGHTS	3	3	2	2	2	2	2					
					10. SUICIDAL THOUGHTS	2	2	2	1	1	1	1					
					11. Total score	29	28	25	22	20	19	19					
530	Imipramine	Female	2	01. APPARENT SADNESS	4	4	3	3	2	2	2	2					
				02. REPORTED SADNESS	3	3	3	2	2	2	2						
				03. INNER TENSION	3	3	3	3	3	3	3						
				04. REDUCED SLEEP	5	4	3	3	3	3	3						
				05. REDUCED APPETITE	2	2	1	1	1	1	1						
				06. CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	2	2						
				07. LASSITUDE	3	3	2	2	2	1	2						
				08. INABILITY TO FEEL	2	2	3	2	2	2	2						
				09. PESSIMISTIC THOUGHTS	3	3	2	2	2	2	2						
				10. SUICIDAL THOUGHTS	2	2	2	1	1	1	1						
				11. Total score	29	28	25	22	20	19	19						
531	Reboxetine	Female	2	01. APPARENT SADNESS	4	4	4	2	2	2	2						
				02. REPORTED SADNESS	4	4	3	3	3	3	2						

1367

9550082

59

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
7/07	531	Reboxetine	Female	2	09. INNER TENSION	3	3	2	2	1	1	2					
					04. REDUCED SLEEP	4	3	2	2	2	1	1					
					05. REDUCED APPETITE	1	2	0	1	1	1	0					
					06. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2					
					07. LASSITUDE	2	2	2	2	2	2	1					
					08. INABILITY TO FEEL	3	2	2	3	3	2	2					
					09. PESSIMISTIC THOUGHTS	4	3	3	3	3	3	2					
					10. SUICIDAL THOUGHTS	2	2	2	0	0	0	0					
					11. Total score	29	27	22	20	19	17	14					
					532	Imipramine	Female	2	01. APPARENT SADNESS	4	3	4	4	3	3	3	2
									02. REPORTED SADNESS	3	3	3	3	3	3	2	
03. INNER TENSION	3	3	3	3					3	2	1						
04. REDUCED SLEEP	4	4	2	2					3	4	2						
05. REDUCED APPETITE	4	4	4	2					1	2	1						
06. CONCENTRATIONS DIFFICULTIES	4	4	4	3					3	3	2						
07. LASSITUDE	3	3	3	3					3	3	2						
08. INABILITY TO FEEL	3	3	3	3					2	3	2						
09. PESSIMISTIC THOUGHTS	3	3	3	3					2	2	2						
10. SUICIDAL THOUGHTS	1	1	2	2					0	2	0						
11. Total score	32	31	29	28					24	27	16						
533	Reboxetine	Male	2	01. APPARENT SADNESS	4	4	4	4	3	3	3	3					
				02. REPORTED SADNESS	3	3	4	3	3	3	2						
				03. INNER TENSION	3	4	3	3	3	2	2						
				04. REDUCED SLEEP	4	4	4	3	3	3	3						
				05. REDUCED APPETITE	2	4	4	2	2	1	0						
				06. CONCENTRATIONS DIFFICULTIES	4	4	4	3	3	2	2						
				07. LASSITUDE	2	3	2	3	2	2	3						
				08. INABILITY TO FEEL	3	3	3	3	2	2	2						
				09. PESSIMISTIC THOUGHTS	3	3	3	3	3	2	2						
				10. SUICIDAL THOUGHTS	4	2	3	3	1	2	1						
				11. Total score	32	33	34	30	25	22	20						
534	Placebo	Female	2	01. APPARENT SADNESS	4	4	4	4	3	3	3	2					
				02. REPORTED SADNESS	3	3	3	3	3	2	2						
				03. INNER TENSION	3	3	3	3	2	2	1						
				04. REDUCED SLEEP	3	3	3	3	3	2	2						
				05. REDUCED APPETITE	3	3	2	2	2	0	1						
				06. CONCENTRATIONS DIFFICULTIES	3	3	3	2	2	2	2						
				07. LASSITUDE	3	3	3	3	3	2	2						
				08. INABILITY TO FEEL	3	3	3	3	2	2	2						
				09. PESSIMISTIC THOUGHTS	3	3	3	3	2	2	2						
				10. SUICIDAL THOUGHTS	2	2	1	1	2	1	0						
				11. Total score	30	29	27	25	24	16	16						
8	211	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	3									

1368

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60

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PHARRACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.9

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	211	Reboxetine	Female	1	02. INNER TENSION	2	2	2	2	2	2	2
					03. APPARENT SADNESS	2	2	2	2	2	2	
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1	
					05. INERTIA	2	2	2	2	2	2	
					06. INABILITY TO FEEL	2	2	2	2	2	2	
					07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	
					09. REDUCED SLEEP	1	1	1	1	1	1	
					10. REDUCED APPETITE	1	1	1	1	1	1	
					11. Total score	16	16	16	19			
						212	Placebo	Female	1	01. REPORTED SADNESS	2	2
02. INNER TENSION	2	2	2	2						2	2	
03. APPARENT SADNESS	2	2	2	2						2	2	
04. SUICIDAL THOUGHTS	1	1	1	1						1	1	
05. INERTIA	2	2	2	2						2	2	
06. INABILITY TO FEEL	2	2	2	2						2	2	
07. PESSIMISTIC THOUGHTS	1	1	1	1						1	1	
08. CONCENTRATIONS DIFFICULTIES	1	1	1	1						1	1	
09. REDUCED SLEEP	1	1	1	1						1	1	
10. REDUCED APPETITE	1	1	1	1						1	1	
11. Total score	15	15	15	16						16	16	
	213	Imipramine	Male	1	01. REPORTED SADNESS	2						
					02. INNER TENSION	2						
					03. APPARENT SADNESS	2						
					04. SUICIDAL THOUGHTS	1						
					05. INERTIA	1						
					06. INABILITY TO FEEL	2						
					07. PESSIMISTIC THOUGHTS	2						
					08. CONCENTRATIONS DIFFICULTIES	1						
					09. REDUCED SLEEP	1						
					10. REDUCED APPETITE	1						
					11. Total score	15						
	214	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	2	2	2	2	2
					02. INNER TENSION	1	1	1	1	1	1	
					03. APPARENT SADNESS	1	1	1	1	1	1	
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05. INERTIA	2	2	2	2	2	2	
					06. INABILITY TO FEEL	1	1	1	1	1	1	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	
					09. REDUCED SLEEP	2	2	2	2	2	2	
					10. REDUCED APPETITE	1	1	1	1	1	1	
					11. Total score	13	13	13	12	12	12	

1369

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61

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012a/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	215	Placebo	Female	1	01.REPORTED SADNESS	2	1	2	1	1	0	0
					02.INNER TENSION	1	1	1	0	0	0	
					03.APPARENT SADNESS	1	1	2	1	1	0	
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05.INERTIA	2	2	2	1	1	1	
					06.INABILITY TO FEEL	1	1	2	1	0	0	
					07.PESSIMISTIC THOUGHTS	0	0	1	1	0	0	
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	0	
					09.REDUCED SLEEP	1	1	1	1	0	0	
					10.REDUCED APPETITE	2	1	1	0	0	0	
					11.Total score	11	9	13	6	3	1	
	216	Imipramine	Male	1	01.REPORTED SADNESS	2	2	2	2	2	2	2
					02.INNER TENSION	1	1	1	1	1	1	
					03.APPARENT SADNESS	2	2	2	1	1	1	
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05.INERTIA	2	2	2	2	2	2	
					06.INABILITY TO FEEL	2	2	2	2	2	2	
					07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	
					09.REDUCED SLEEP	1	1	1	1	1	1	
					10.REDUCED APPETITE	0	0	0	0	0	0	
					11.Total score	15	13	13	12	10	10	
	217	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	1	1	1	1	1
					02.INNER TENSION	1	1	1	1	1	1	
					03.APPARENT SADNESS	2	2	1	1	1	0	
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05.INERTIA	2	2	1	1	1	1	
					06.INABILITY TO FEEL	2	2	1	1	1	1	
					07.PESSIMISTIC THOUGHTS	1	1	1	1	0	0	
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	0	
					09.REDUCED SLEEP	1	0	0	0	0	0	
					10.REDUCED APPETITE	1	0	0	0	0	0	
					11.Total score	13	10	7	6	5	4	
	218	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2	1	1
					02.INNER TENSION	2	2	2	1	1	1	
					03.APPARENT SADNESS	2	2	2	2	2	1	
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05.INERTIA	2	2	2	2	1	1	
					06.INABILITY TO FEEL	2	2	2	2	1	1	
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1	1	
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	
					09.REDUCED SLEEP	1	1	1	1	1	0	
					10.REDUCED APPETITE	1	1	1	1	0	0	
					11.Total score	16	16	16	13	9	7	

1370

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62

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PHARMAZIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	219	Placebo	Female	1	01. REPORTED SADNESS	1	1	1	1	1		
					02. INNER TENSION	1	1	1	1	1		
					03. APPARENT SADNESS	1	1	1	1	1		
					04. SUICIDAL THOUGHTS	0	0	0	0	0		
					05. INERTIA	2	2	2	2	2		
					06. INABILITY TO FEEL	2	2	2	2	2		
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1		
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		
					09. REDUCED SLEEP	1	1	1	1	1		
					10. REDUCED APPETITE	1	1	1	1	1		
					11. Total score	11	11	9	7			
220	220	Imipramine	Female	1	01. REPORTED SADNESS	2	2	2	2	1	1	1
					02. INNER TENSION	2	2	2	2	1	1	1
					03. APPARENT SADNESS	2	2	2	2	1	1	1
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					05. INERTIA	2	2	2	2	2	2	2
					06. INABILITY TO FEEL	2	2	2	2	2	2	2
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
					09. REDUCED SLEEP	1	1	1	1	1	1	1
					10. REDUCED APPETITE	1	1	1	1	1	1	1
					11. Total score	14	14	14	10	10	10	7
221	221	Imipramine	Male	1	01. REPORTED SADNESS	2	2	2	2	1	1	1
					02. INNER TENSION	2	2	2	2	1	1	1
					03. APPARENT SADNESS	2	2	2	2	1	1	1
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					05. INERTIA	2	2	2	2	2	2	2
					06. INABILITY TO FEEL	2	2	2	2	2	2	2
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
					09. REDUCED SLEEP	1	1	1	1	1	1	1
					10. REDUCED APPETITE	1	1	1	1	1	1	1
					11. Total score	14	14	14	10	10	10	7
222	222	Placebo	Female	1	01. REPORTED SADNESS	1	0	0	0	0	0	0
					02. INNER TENSION	1	1	0	0	0	0	0
					03. APPARENT SADNESS	1	0	0	0	0	0	0
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0
					05. INERTIA	1	1	1	1	0	0	0
					06. INABILITY TO FEEL	1	1	1	1	0	0	0
					07. PESSIMISTIC THOUGHTS	1	1	1	1	0	0	0
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0	0
					09. REDUCED SLEEP	1	1	1	1	0	0	0
					10. REDUCED APPETITE	1	0	0	0	0	0	0
					11. Total score	14	14	12	10	7	7	5

1371

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63

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	222	Placebo	Female	1	9	5	3	2	0	1	1
					11.Total score						
	223	Imipramine	Female	1	2	2	1	1	1	1	1
					01.REPORTED SADNESS						
					02.INNER TENSION						
					03.APPARENT SADNESS						
					04.SUICIDAL THOUGHTS						
					05.INERTIA						
					06.INABILITY TO FEEL						
					07.PESSIMISTIC THOUGHTS						
					08.CONCENTRATIONS DIFFICULTIES						
					09.REDUCED SLEEP						
					10.REDUCED APPETITE						
					14	14	11	9	6	5	5
					11.Total score						
	224	Placebo	Female	1	2	2	2	2	2	1	1
					01.REPORTED SADNESS						
					02.INNER TENSION						
					03.APPARENT SADNESS						
					04.SUICIDAL THOUGHTS						
					05.INERTIA						
					06.INABILITY TO FEEL						
					07.PESSIMISTIC THOUGHTS						
					08.CONCENTRATIONS DIFFICULTIES						
					09.REDUCED SLEEP						
					10.REDUCED APPETITE						
					13	13	11	10	10	8	7
					11.Total score						
	225	Placebo	Male	1	2	2	2	2	2	2	1
					01.REPORTED SADNESS						
					02.INNER TENSION						
					03.APPARENT SADNESS						
					04.SUICIDAL THOUGHTS						
					05.INERTIA						
					06.INABILITY TO FEEL						
					07.PESSIMISTIC THOUGHTS						
					08.CONCENTRATIONS DIFFICULTIES						
					09.REDUCED SLEEP						
					10.REDUCED APPETITE						
					12	14	14	14	12	11	8
					11.Total score						
	226	Reboxetine	Male	1	2	2	2	2	2	2	2
					01.REPORTED SADNESS						
					02.INNER TENSION						
					03.APPARENT SADNESS						
					04.SUICIDAL THOUGHTS						
					05.INERTIA						
					06.INABILITY TO FEEL						
					07.PESSIMISTIC THOUGHTS						
					08.CONCENTRATIONS DIFFICULTIES						
					09.REDUCED SLEEP						

1372

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64

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
8	226	Reboxetine	Male	1	10. REDUCED APPETITE	1	1	1	1	1	1	1	
					11. Total score	15	15	15	15	15	15	15	
	227	Reboxetine	Male	1	01. REPORTED SADNESS	2	2	2	2	2	2	2	2
					02. INNER TENSION	2	2	2	2	2	2	2	
					03. APPARENT SADNESS	2	2	2	2	2	2	2	
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0	
					05. INERTIA	2	2	2	2	2	2	2	
					06. INABILITY TO FEEL	2	2	2	2	2	2	2	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	
					09. REDUCED SLEEP	1	1	1	1	1	1	1	
10. REDUCED APPETITE	1	1	1	1	1	1	1						
11. Total score	14	14	13	13	13	13	13						
228	Imipramine	Male	1	01. REPORTED SADNESS	2	2	2	2	2	2	2	2	
				02. INNER TENSION	2	2	2	2	2	2	2		
				03. APPARENT SADNESS	2	2	2	2	2	2	2		
				04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0		
				05. INERTIA	2	2	2	2	2	2	2		
				06. INABILITY TO FEEL	2	2	2	2	2	2	2		
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1		
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1		
				09. REDUCED SLEEP	2	2	2	2	2	2	2		
				10. REDUCED APPETITE	1	1	1	1	1	1	1		
				11. Total score	15	15	15	15	15	15	15		
229	Imipramine	Female	1	01. REPORTED SADNESS	2	2	2	2	2	2	2	2	
				02. INNER TENSION	2	2	2	2	2	2	2		
				03. APPARENT SADNESS	2	2	2	2	2	2	2		
				04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0		
				05. INERTIA	2	2	2	2	2	2	2		
				06. INABILITY TO FEEL	2	2	2	2	2	2	2		
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1		
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1		
				09. REDUCED SLEEP	2	2	2	2	2	2	2		
				10. REDUCED APPETITE	1	1	1	1	1	1	1		
				11. Total score	15	15	14	13	12	12	8		
230	Reboxetine	Female	1	01. REPORTED SADNESS	3	3	3	3	3	3	3	3	
				02. INNER TENSION	2	2	2	2	2	2	2		
				03. APPARENT SADNESS	2	2	2	2	2	2	2		
				04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0		
				05. INERTIA	2	2	2	2	2	2	2		
				06. INABILITY TO FEEL	2	2	2	2	2	2	2		
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1		
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1		

1373

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65

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PHARMAZIA CNS R2D
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centro	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
B	230	Reboxetine	Female	1	09. REDUCED SLEEP	2	2	2	2	1	1	1
					10. REDUCED APPETITE	1	1	1	1	1	1	
					11. Total score	16	16	16	15	13	13	
B	231	Imipramine	Male	1	01. REPORTED SADNESS	2	2	1	1	1	1	1
					02. INNER TENSION	1	1	1	1	1	1	
					03. APPARENT SADNESS	2	2	1	1	1	1	
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05. INERTIA	2	2	2	2	1	1	
					06. INABILITY TO FEEL	2	2	2	2	1	1	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	0	0	
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	
					09. REDUCED SLEEP	2	2	1	1	1	1	
					10. REDUCED APPETITE	1	1	1	1	1	0	
					11. Total score	14	14	11	10	8	7	
B	232	Reboxetine	Male	1	01. REPORTED SADNESS	2	2	2	2	2	1	1
					02. INNER TENSION	1	1	1	1	1	1	
					03. APPARENT SADNESS	2	2	2	2	2	1	
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05. INERTIA	2	2	2	2	2	1	
					06. INABILITY TO FEEL	2	2	2	2	2	1	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	0	
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	
					09. REDUCED SLEEP	1	1	1	1	1	1	
					10. REDUCED APPETITE	1	1	1	1	1	0	
					11. Total score	13	13	13	13	12	7	
B	233	Placebo	Female	1	01. REPORTED SADNESS	2	2	2	2	1	1	1
					02. INNER TENSION	2	2	2	2	1	1	
					03. APPARENT SADNESS	2	2	2	2	1	1	
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05. INERTIA	2	2	2	2	2	1	
					06. INABILITY TO FEEL	1	1	1	1	1	1	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	0	
					09. REDUCED SLEEP	2	2	2	2	1	1	
					10. REDUCED APPETITE	1	1	1	1	1	0	
					11. Total score	15	15	15	15	11	10	
B	234	Placebo	Female	1	01. REPORTED SADNESS	2	2	2	2	2	2	2
					02. INNER TENSION	2	2	2	2	1	1	
					03. APPARENT SADNESS	2	2	2	2	2	1	
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0	
					05. INERTIA	2	2	2	2	2	2	
					06. INABILITY TO FEEL	2	2	2	2	2	2	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	

1374

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66

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0
MONTGOMERY ASSBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Assberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	234	Placebo	Female	1	08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
					09. REDUCED SLEEP	1	1	1	1	1	1	
					10. REDUCED APPETITE	1	1	1	1	1	1	
					11. Total score	14	14	14	13	13	12	
8/A	235	Placebo	Female	1	01. REPORTED SADNESS	3	2	2	2	1	1	1
					02. INNER TENSION	2	2	2	1	1	1	
					03. APPARENT SADNESS	2	2	2	2	2	1	
					04. SUICIDAL THOUGHTS	1	1	1	1	0	0	
					05. INERTIA	3	2	1	1	1	1	
					06. INABILITY TO FEEL	2	2	1	1	1	1	
					07. PESSIMISTIC THOUGHTS	2	2	2	2	1	1	
					08. CONCENTRATIONS DIFFICULTIES	3	2	2	2	2	1	
					09. REDUCED SLEEP	3	2	1	1	1	1	
					10. REDUCED APPETITE	2	2	2	1	1	1	
					11. Total score	25	19	16	13	11	9	
1375	236	Placebo	Female	1	01. REPORTED SADNESS	3	2	2	1	1	1	1
					02. INNER TENSION	2	1	1	1	1	0	
					03. APPARENT SADNESS	3	2	1	1	1	0	
					04. SUICIDAL THOUGHTS	1	1	0	0	0	0	
					05. INERTIA	2	1	1	1	1	1	
					06. INABILITY TO FEEL	2	1	1	1	1	1	
					07. PESSIMISTIC THOUGHTS	3	2	1	1	1	1	
					08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	
					09. REDUCED SLEEP	3	3	2	1	1	1	
					10. REDUCED APPETITE	2	2	2	1	1	1	
					11. Total score	23	17	12	9	9	8	
237	Reboxetine	Female	1	1	01. REPORTED SADNESS	3	2	1	1	0	0	0
					02. INNER TENSION	2	2	2	1	1	1	
					03. APPARENT SADNESS	2	2	2	1	1	1	
					04. SUICIDAL THOUGHTS	1	1	1	1	1	0	
					05. INERTIA	2	2	1	1	1	1	
					06. INABILITY TO FEEL	2	2	1	1	1	1	
					07. PESSIMISTIC THOUGHTS	3	2	1	1	1	1	
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	0	
					09. REDUCED SLEEP	3	2	2	1	2	1	
					10. REDUCED APPETITE	3	2	2	1	1	1	
					11. Total score	23	19	14	10	10	9	
238	Reboxetine	Female	1	1	01. REPORTED SADNESS	3	2	1	0	0	0	
					02. INNER TENSION	2	2	1	1	1	1	
					03. APPARENT SADNESS	2	2	1	1	0	0	
					04. SUICIDAL THOUGHTS	1	1	1	1	0	0	
					05. INERTIA	3	2	1	1	1	1	
					06. INABILITY TO FEEL	2	2	1	1	1	1	

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67

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49					
S/A	238	Reboxetine	Female	1	07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1	0				
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1					
					09.REDUCED SLEEP	2	2	1	1	1	1	1					
					10.REDUCED APPETITE	2	2	1	1	1	1	1					
					11.Total score	21	18	11	9	7	7	6					
					239	Imipramine	Female	1	01.REPORTED SADNESS	3	2	2	1	1	1	1	1
									02.INNER TENSION	2	2	1	1	1	1	1	
									03.APPARENT SADNESS	2	2	1	1	0	0	1	
									04.SUICIDAL THOUGHTS	1	1	1	1	0	0	1	
									05.INERTIA	2	2	2	2	1	1	0	
									06.INABILITY TO FEEL	2	2	1	1	1	1	1	
07.PESSIMISTIC THOUGHTS	2	2	2	1					1	1	1						
08.CONCENTRATIONS DIFFICULTIES	2	2	1	1					1	1	1						
09.REDUCED SLEEP	2	2	1	1					1	1	1						
10.REDUCED APPETITE	3	2	2	2					1	1	0						
11.Total score	21	17	14	11					8	7	7						
240	Imipramine	Female	1	01.REPORTED SADNESS	3	2	2	1	1	1	1	1					
				02.INNER TENSION	2	2	2	1	2	2	2						
				03.APPARENT SADNESS	3	3	2	2	2	2	1						
				04.SUICIDAL THOUGHTS	1	1	0	1	0	0	0						
				05.INERTIA	2	2	2	2	2	2	1						
				06.INABILITY TO FEEL	2	2	2	2	2	2	2						
				07.PESSIMISTIC THOUGHTS	3	2	2	2	2	2	1						
				08.CONCENTRATIONS DIFFICULTIES	3	2	2	2	2	2	2						
				09.REDUCED SLEEP	3	3	3	3	3	2	2						
				10.REDUCED APPETITE	2	2	1	1	1	1	1						
				11.Total score	24	21	18	17	16	16	12						
553	Placebo	Female	1	01.REPORTED SADNESS	2	2	1	1	1	1	1	1					
				02.INNER TENSION	2	2	2	1	2	2	1						
				03.APPARENT SADNESS	2	1	1	1	1	1	1						
				04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1						
				05.INERTIA	2	2	2	1	1	1	1						
				06.INABILITY TO FEEL	3	2	2	2	2	2	1						
				07.PESSIMISTIC THOUGHTS	3	2	2	2	2	2	1						
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1						
				09.REDUCED SLEEP	3	3	3	2	2	2	2						
				10.REDUCED APPETITE	2	2	2	1	1	1	1						
				11.Total score	22	19	18	15	12	11	12						
554	Reboxetine	Male	1	01.REPORTED SADNESS	3	2	2	1	0	0	0	0					
				02.INNER TENSION	2	2	2	1	1	1	0						
				03.APPARENT SADNESS	3	2	2	1	1	0	0						
				04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0						
				05.INERTIA	2	2	1	1	1	1	1						

1376

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68

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
8/A	554	Reboxetine	Male	1	06. INABILITY TO FEEL	3	3	2	2	2	2	1	1				
					07. PESSIMISTIC THOUGHTS	3	2	2	1	1	1	1					
					08. CONCENTRATIONS DIFFICULTIES	3	3	2	2	1	1	0					
					09. REDUCED SLEEP	3	3	2	2	1	1	1					
					10. REDUCED APPETITE	2	2	1	1	1	1	1					
					11. Total score	25	22	17	12	8	6	5					
					555	Reboxetine	Female	1	01. REPORTED SADNESS	2	1	1	1	1	1	1	1
									02. INNER TENSION	2	1	1	1	1	1	1	
									03. APPARENT SADNESS	3	2	1	1	1	1	1	
									04. SUICIDAL THOUGHTS	1	1	1	1	0	0	0	
									05. INERTIA	2	2	2	2	1	1	1	
06. INABILITY TO FEEL	2	2	2	1					1	1	1						
07. PESSIMISTIC THOUGHTS	2	2	2	1					1	1	1						
08. CONCENTRATIONS DIFFICULTIES	2	2	2	1					1	1	1						
09. REDUCED SLEEP	3	3	2	2					2	1	2						
10. REDUCED APPETITE	2	2	1	1					1	1	1						
11. Total score	21	18	13	12					9	10	9						
9	241	Placebo	Female	1	01. REPORTED SADNESS	2	2	1	1	1	1	0	0				
					02. INNER TENSION	2	2	1	0	0	0	0					
					03. APPARENT SADNESS	2	2	1	1	1	1	1					
					04. SUICIDAL THOUGHTS	1	1	1	0	0	0	0					
					05. INERTIA	2	2	1	1	1	1	1					
					06. INABILITY TO FEEL	2	2	1	1	1	1	0					
					07. PESSIMISTIC THOUGHTS	3	2	2	1	1	1	1					
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1					
					09. REDUCED SLEEP	3	3	2	2	2	2	2					
					10. REDUCED APPETITE	2	2	2	2	1	1	1					
					11. Total score	21	20	14	10	9	8	5					
9	242	Reboxetine	Female	1	01. REPORTED SADNESS	3	3	3	3	3	3	3	2				
					02. INNER TENSION	2	2	2	2	2	2	2					
					03. APPARENT SADNESS	2	2	2	2	2	2	2					
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1					
					05. INERTIA	2	2	2	2	2	2	2					
					06. INABILITY TO FEEL	2	2	2	2	2	2	2					
					07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2					
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2					
					09. REDUCED SLEEP	2	2	2	2	2	2	2					
					10. REDUCED APPETITE	2	2	2	2	2	2	2					
					11. Total score	19	20	23	23	23	23	23					

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69

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
9	242	Reboxetine	Female	1	05. INERTIA	2	1	1	1							
					06. INABILITY TO FEEL	2	1	1	2	1						
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1						
					08. CONCENTRATIONS DIFFICULTIES	2	1	2	2	1						
					09. REDUCED SLEEP	2	2	2	2	2						
					10. REDUCED APPETITE	1	0	0	1							
					11. Total score	17	10	15	15							
					243	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	2				
									02. INNER TENSION	2	3	3				
									03. APPARENT SADNESS	2	2	2				
									04. SUICIDAL THOUGHTS	1	1	1				
05. INERTIA	2	2	2													
06. INABILITY TO FEEL	1	2	2													
07. PESSIMISTIC THOUGHTS	2	2	2													
08. CONCENTRATIONS DIFFICULTIES	1	1	3													
09. REDUCED SLEEP	1	1	3													
10. REDUCED APPETITE	1	1	2													
11. Total score	15	18	22													
244	Imipramine	Female	1	01. REPORTED SADNESS	2	2	1	1								
				02. INNER TENSION	1	1	1	1								
				03. APPARENT SADNESS	2	1	1	1								
				04. SUICIDAL THOUGHTS	2	0	0	0								
				05. INERTIA	2	2	1	1								
				06. INABILITY TO FEEL	2	2	1	1								
				07. PESSIMISTIC THOUGHTS	0	0	0	0								
				08. CONCENTRATIONS DIFFICULTIES	2	2	1	1								
				09. REDUCED SLEEP	2	2	1	1								
				10. REDUCED APPETITE	1	0	0	0								
				11. Total score	16	12	7	7								
245	Imipramine	Female	1	01. REPORTED SADNESS	2	2	1	0	0	0	0					
				02. INNER TENSION	2	2	2	1	1	1						
				03. APPARENT SADNESS	1	1	0	0	0	0						
				04. SUICIDAL THOUGHTS	1	1	0	0	0	0						
				05. INERTIA	2	1	0	0	0	0						
				06. INABILITY TO FEEL	1	1	0	0	0	0						
				07. PESSIMISTIC THOUGHTS	2	2	0	0	0	0						
				08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	0	0						
				09. REDUCED SLEEP	1	1	2	1	2	2						
				10. REDUCED APPETITE	1	1	0	0	0	0						
				11. Total score	14	13	6	2	3	4						
246	Placebo	Female	1	01. REPORTED SADNESS	3	3	3	3	3	3	3					
				02. INNER TENSION	3	3	3	3	3	3						
				03. APPARENT SADNESS	3	3	3	3	3	3						

1378

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70

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PHARMACIA CMS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
9	246	Placebo	Female	1	04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1					
					05. INERTIA	3	3	3	3	3	3						
					06. INABILITY TO FEEL	3	3	3	3	3	3						
					07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2						
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2						
					09. REDUCED SLEEP	2	2	2	2	2	2						
					10. REDUCED APPETITE	2	2	2	2	2	2						
					11. Total score	24	24	24	24	24	25						
					247	247	Placebo	Female	1	01. REPORTED SADNESS	2	2	2	2	2	2	2
										02. INNER TENSION	2	2	1	2	2	2	
										03. APPARENT SADNESS	1	1	1	1	2	2	
04. SUICIDAL THOUGHTS	1	1	1	1						1	1						
05. INERTIA	2	2	1	1						1	1						
06. INABILITY TO FEEL	1	1	1	1						1	2						
07. PESSIMISTIC THOUGHTS	1	1	2	1						1	1						
08. CONCENTRATIONS DIFFICULTIES	2	2	1	1						1	1						
09. REDUCED SLEEP	2	2	2	1						1	2						
10. REDUCED APPETITE	1	1	1	1						1	1						
11. Total score	15	16	12	14						15	15						
248	248	Placebo	Male	1	01. REPORTED SADNESS	2	2	2	2	2	2	2					
					02. INNER TENSION	1	2	2	3	3	3						
					03. APPARENT SADNESS	2	2	2	2	2	2						
					04. SUICIDAL THOUGHTS	1	1	1	2	2	2						
					05. INERTIA	2	2	2	2	2	2						
					06. INABILITY TO FEEL	2	2	2	2	2	2						
					07. PESSIMISTIC THOUGHTS	1	1	1	2	2	2						
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2						
					09. REDUCED SLEEP	2	2	2	2	2	2						
					10. REDUCED APPETITE	1	1	1	1	1	1						
					11. Total score	16	17	15	17	16	17						
249	249	Reboxetine	Female	1	01. REPORTED SADNESS	3	3	3	3	3	3	3					
					02. INNER TENSION	1	1	1	1	1	1						
					03. APPARENT SADNESS	3	3	3	3	3	3						
					04. SUICIDAL THOUGHTS	0	0	0	0	0	0						
					05. INERTIA	1	1	1	1	1	1						
					06. INABILITY TO FEEL	1	1	1	1	1	1						
					07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2						
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1						
					09. REDUCED SLEEP	1	1	1	1	1	1						
					10. REDUCED APPETITE	1	1	1	1	1	1						
					11. Total score	15	15	15	15	15	15						
250	250	Imipramine	Female	1	01. REPORTED SADNESS	3	3	3	3	3	3						
					02. INNER TENSION	1	1	1	1	1	1						

1379

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71

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PHARMACIA CRS R&D
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 13.0

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9	250	Imipramine	Female	1	05. APPARENT SADNESS	2	2	2	2	2	2	2				
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1					
					05. INERTIA	2	2	2	2	2	2					
					06. INABILITY TO FEEL	3	3	3	3	3	3					
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1					
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2					
					09. REDUCED SLEEP	2	2	2	2	2	2					
					10. REDUCED APPETITE	2	2	2	2	2	2					
					11. Total score	19	19	20	20	20	20					
					251	Imipramine	Female	1	01. REPORTED SADNESS	3	1	2	2	0	0	0
									02. INNER TENSION	2	1	1	1	0	0	
03. APPARENT SADNESS	3	1	2	0					0	0						
04. SUICIDAL THOUGHTS	2	1	2	0					0							
05. INERTIA	1	2	2	1					1							
06. INABILITY TO FEEL	2	1	2	0					0							
07. PESSIMISTIC THOUGHTS	2	2	2	0					0							
08. CONCENTRATIONS DIFFICULTIES	2	1	1	0					0							
09. REDUCED SLEEP	2	1	1	1					1							
10. REDUCED APPETITE	1	2	1	1					1							
11. Total score	20	12	16	2					2							
252	Reboxetine	Female	1	01. REPORTED SADNESS	2	3	3	3	3	3	3					
				02. INNER TENSION	1	2	2	2	3	3						
				03. APPARENT SADNESS	1	1	1	1	1	1						
				04. SUICIDAL THOUGHTS	2	2	2	2	2	2						
				05. INERTIA	2	2	2	2	2	2						
				06. INABILITY TO FEEL	1	1	1	1	1	1						
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1						
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2						
				09. REDUCED SLEEP	2	3	3	3	3	3						
				10. REDUCED APPETITE	1	1	1	1	1	1						
				11. Total score	14	18	19	19	20							
253	Reboxetine	Female	1	01. REPORTED SADNESS	3	3	3	3	3	3	3					
				02. INNER TENSION	1	1	1	1	1	1						
				03. APPARENT SADNESS	2	2	2	2	2	2						
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1						
				05. INERTIA	2	2	2	2	2	2						
				06. INABILITY TO FEEL	2	2	2	2	2	2						
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1						
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2						
				09. REDUCED SLEEP	2	2	2	2	2	2						
				10. REDUCED APPETITE	1	1	1	1	1	1						
				11. Total score	17	21	21	21	21							
254	Imipramine	Female	1	01. REPORTED SADNESS	3	3	3	3	3	3	3					

1380

9550082

72

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	254	Imipramine	Female	1	02.INNER TENSION	2	3	3				
					03.APPARENT SADNESS	2	3	3				
					04.SUICIDAL THOUGHTS	2	2	2				
					05.INERTIA	2	3	3				
					06.INABILITY TO FEEL	1	1	1				
					07.PESSIMISTIC THOUGHTS	1	1	1				
					08.CONCENTRATIONS DIFFICULTIES	1	1	1				
					09.REDUCED SLEEP	2	3	3				
					10.REDUCED APPETITE	1	1	1				
					11.Total score	17	21	21				
					255	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2
02.INNER TENSION	2	2	2	3					3			
03.APPARENT SADNESS	1	1	1	2					2			
04.SUICIDAL THOUGHTS	2	2	2	2					2			
05.INERTIA	3	3	3	2					2			
06.INABILITY TO FEEL	2	2	2	3					3			
07.PESSIMISTIC THOUGHTS	1	1	1	1					1			
08.CONCENTRATIONS DIFFICULTIES	3	3	3	3					3			
09.REDUCED SLEEP	1	1	1	3					3			
10.REDUCED APPETITE	0	0	0	0					0			
11.Total score	17	17	20	20					23			
256	Imipramine	Female	1	01.REPORTED SADNESS	3	3	3	1	1	3		1
				02.INNER TENSION	2	2	2	1	1	2		1
				03.APPARENT SADNESS	3	3	3	0	0	3		1
				04.SUICIDAL THOUGHTS	2	2	2	0	0	2		1
				05.INERTIA	3	3	3	1	1	3		1
				06.INABILITY TO FEEL	3	3	3	1	1	3		1
				07.PESSIMISTIC THOUGHTS	2	2	2	0	0	2		0
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	2		1
				09.REDUCED SLEEP	2	2	2	2	2	2		1
				10.REDUCED APPETITE	2	2	2	1	1	2		1
				11.Total score	24	24	24	8	8	21		9
257	Placebo	Male	1	01.REPORTED SADNESS	2	2	2					
				02.INNER TENSION	2	2	2					
				03.APPARENT SADNESS	1	1	1					
				04.SUICIDAL THOUGHTS	2	2	2					
				05.INERTIA	2	2	2					
				06.INABILITY TO FEEL	2	2	2					
				07.PESSIMISTIC THOUGHTS	2	2	2					
				08.CONCENTRATIONS DIFFICULTIES	1	1	1					
				09.REDUCED SLEEP	2	2	2					
				10.REDUCED APPETITE	1	1	1					
				11.Total score	17	17	17					

1381

9550082

73

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
9	258	Placebo	Male	1	01.REPORTED SADNESS	3	3	3						
					02.INNER TENSION	2	3	3						
					03.APPARENT SADNESS	2	2	2						
					04.SUICIDAL THOUGHTS	1	1	1						
					05.INERTIA	3	3	3						
					06.INABILITY TO FEEL	1	1	1						
					07.PESSIMISTIC THOUGHTS	2	2	2						
					08.CONCENTRATIONS DIFFICULTIES	2	2	2						
					09.REDUCED SLEEP	2	3	3						
					10.REDUCED APPETITE	1	1	1						
					11.Total score	19	24	21						
11	319	Placebo	Male	1	01.REPORTED SADNESS	2	2	2	2	2	2	2	1	
					02.INNER TENSION	1	1	1	2	2	2	2	2	2
					03.APPARENT SADNESS	2	2	2	2	2	2	2	2	2
					04.SUICIDAL THOUGHTS	2	2	2	2	2	2	2	2	2
					05.INERTIA	1	1	1	1	1	1	1	1	1
					06.INABILITY TO FEEL	2	2	2	2	2	2	2	2	2
					07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2	2	2
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	2	2
					09.REDUCED SLEEP	2	2	2	2	2	2	2	2	2
					10.REDUCED APPETITE	1	1	1	1	1	1	1	1	1
					11.Total score	17	16	17	18	18	18	16	16	13
320	Imipramine	Male	1	01.REPORTED SADNESS	2	3	2	2	2	1	2	1		
				02.INNER TENSION	2	2	2	2	2	1	2	1	1	
				03.APPARENT SADNESS	2	2	2	1	2	1	2	1	1	
				04.SUICIDAL THOUGHTS	1	1	1	2	1	1	1	1	1	
				05.INERTIA	2	2	2	2	2	1	2	1	2	
				06.INABILITY TO FEEL	1	2	1	2	1	2	1	1	0	
				07.PESSIMISTIC THOUGHTS	2	2	2	2	2	1	3	1	2	
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	2	1	2	
				09.REDUCED SLEEP	3	3	3	2	2	1	2	2	2	
				10.REDUCED APPETITE	0	2	0	0	0	0	0	0	0	
				11.Total score	17	21	13	13	18	10	15	10	10	
321	Placebo	Male	1	01.REPORTED SADNESS	2	2	2	1	1	0	0	0		
				02.INNER TENSION	1	1	1	1	1	1	1	1	1	
				03.APPARENT SADNESS	1	1	1	1	1	0	1	0	0	
				04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0	0	0	
				05.INERTIA	1	1	1	1	1	1	1	0	0	
				06.INABILITY TO FEEL	1	1	1	1	1	0	0	0	0	
				07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	1	
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1	0	0	
				09.REDUCED SLEEP	2	2	2	1	1	1	1	0	0	
				10.REDUCED APPETITE	1	1	1	0	0	0	0	0	0	
				11.Total score	13	13	9	9	5	3	2	2	2	

9550082

74

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Center	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
11	322	Reboxetine	Female	1	01. REPORTED SADNESS	2	1	1	1	1	1	2	2	
					02. INNER TENSION	2	1	1	1	1	1	1	1	1
					03. APPARENT SADNESS	2	1	1	1	1	1	1	1	1
					04. SUICIDAL THOUGHTS	2	1	1	1	1	1	1	1	1
					05. INERTIA	1	2	1	2	2	2	2	2	2
					06. INABILITY TO FEEL	2	1	1	1	1	1	1	1	1
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	1
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	2	2
					09. REDUCED SLEEP	2	2	2	2	2	2	2	2	2
					10. REDUCED APPETITE	1	1	0	0	0	0	0	0	0
					11. Total score	17	14	12	12	12	13	12		
13	323	Reboxetine	Male	2	01. REPORTED SADNESS	2	2	1	1	0	0	0	0	
					02. INNER TENSION	2	2	2	1	2	1	0	0	1
					03. APPARENT SADNESS	2	2	2	2	1	2	1	0	1
					04. SUICIDAL THOUGHTS	4	3	3	2	2	1	2	1	2
					05. INERTIA	2	2	2	0	0	0	0	0	0
					06. INABILITY TO FEEL	2	1	1	1	0	0	0	0	0
					07. PESSIMISTIC THOUGHTS	2	2	2	2	1	2	1	1	1
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	2	2
					09. REDUCED SLEEP	3	2	2	2	2	2	2	2	2
					10. REDUCED APPETITE	2	1	1	0	0	0	0	0	0
					11. Total score	24	19	14	11	6	4	5		
88	324	Imipramine	Male	2	01. REPORTED SADNESS	3	3	3	2	3	3	3	3	
					02. INNER TENSION	4	4	4	3	4	3	3	3	3
					03. APPARENT SADNESS	3	2	2	2	3	3	3	3	3
					04. SUICIDAL THOUGHTS	4	4	4	4	4	4	4	4	4
					05. INERTIA	4	4	4	3	3	3	3	3	3
					06. INABILITY TO FEEL	4	3	3	2	2	2	2	2	2
					07. PESSIMISTIC THOUGHTS	3	3	3	2	2	2	2	2	2
					08. CONCENTRATIONS DIFFICULTIES	3	2	2	2	2	2	2	2	2
					09. REDUCED SLEEP	2	2	2	2	2	2	2	2	2
					10. REDUCED APPETITE	2	2	2	2	2	2	2	2	2
					11. Total score	31	30	27	25	28	27	26		
325	325	Reboxetine	Male	2	01. REPORTED SADNESS	4	1	1	0	0	0	0		
					02. INNER TENSION	4	2	1	0	0	0	0	0	
					03. APPARENT SADNESS	2	2	2	1	1	1	2		
					04. SUICIDAL THOUGHTS	2	4	2	2	0	0	0		
					05. INERTIA	3	3	1	0	0	0	0		
					06. INABILITY TO FEEL	2	2	1	0	0	0	0		
					07. PESSIMISTIC THOUGHTS	3	2	1	1	1	1	1		
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	0	1	1	0		
					09. REDUCED SLEEP	2	2	1	0	0	0	0		
					10. REDUCED APPETITE	2	1	0	0	0	0	0		
					11. Total score	2	1	1	0	0	0	0		

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75

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	325	Reboxetine	Male	2	11.Total score	28	20	12	4	3	3	3
	326	Placebo	Male	2	01.APPARENT SADNESS	5	6	6	5	6	6	6
					02.REPORTED SADNESS	4	5	5	5	6	6	6
					03.INNER TENSION	3	3	4	4	2	2	2
					04.REDUCED SLEEP	5	6	6	5	6	6	6
					05.REDUCED APPETITE	2	3	3	3	4	4	4
					06.CONCENTRATIONS DIFFICULTIES	4	4	4	4	2	2	2
					07.LASSITUDE	3	3	3	3	4	4	4
					08.INABILITY TO FEEL	4	4	4	4	4	4	4
					09.PESSIMISTIC THOUGHTS	3	3	2	2	4	4	4
					10.SUICIDAL THOUGHTS	4	4	4	4	4	4	4
					11.Total score	37	41	41	39	42	40	42
13	327	Imipramine	Male	2	01.APPARENT SADNESS	4	2					
					02.REPORTED SADNESS	3	2					
					03.INNER TENSION	3	2					
					04.REDUCED SLEEP	5	2					
					05.REDUCED APPETITE	2	9					
					06.CONCENTRATIONS DIFFICULTIES	3	3					
					07.LASSITUDE	1	2					
					08.INABILITY TO FEEL	2	2					
					09.PESSIMISTIC THOUGHTS	2	1					
					10.SUICIDAL THOUGHTS	2	1					
					11.Total score	27	17					
328	328	Imipramine	Female	2	01.APPARENT SADNESS	4	2					
					02.REPORTED SADNESS	4	3					
					03.INNER TENSION	4	4					
					04.REDUCED SLEEP	4	3					
					05.REDUCED APPETITE	2	2					
					06.CONCENTRATIONS DIFFICULTIES	3	3					
					07.LASSITUDE	2	2					
					08.INABILITY TO FEEL	3	2					
					09.PESSIMISTIC THOUGHTS	2	2					
					10.SUICIDAL THOUGHTS	3	2					
					11.Total score	31	24					
329	329	Placebo	Female	2	01.APPARENT SADNESS	3	3	3	3	0	0	0
					02.REPORTED SADNESS	4	4	4	3	1	1	0
					03.INNER TENSION	3	4	4	3	3	2	2
					04.REDUCED SLEEP	5	5	5	4	1	0	0
					05.REDUCED APPETITE	0	0	0	0	0	0	0
					06.CONCENTRATIONS DIFFICULTIES	4	4	4	2	2	2	1
					07.LASSITUDE	4	3	3	2	1	0	1
					08.INABILITY TO FEEL	3	3	3	2	0	0	0
					09.PESSIMISTIC THOUGHTS	3	3	3	2	0	0	0

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76

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
11	329	Female	2	10. SUICIDAL THOUGHTS 11. Total score	31	31	31	22	1	8	7	0	8
	330	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL 09. PESSIMISTIC THOUGHTS 10. SUICIDAL THOUGHTS 11. Total score	4	4	4	4	3	3	3	2	0
13	331	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL 09. PESSIMISTIC THOUGHTS 10. SUICIDAL THOUGHTS 11. Total score	3	3	3	2	2	2	2	2	2
00	332	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL 09. PESSIMISTIC THOUGHTS 10. SUICIDAL THOUGHTS 11. Total score	4	3	3	2	0	0	1	0	0
01	333	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL	4	3	3	2	2	2	2	2	2

9550082

77

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS 2&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
11	333	Placebo	Male	2	09. PESSIMISTIC THOUGHTS	3	3	2	2	2	1	1				
					10. SUICIDAL THOUGHTS	2	2	2	1	0	0					
					11. Total score	30	28	27	14	10	10					
					334	Reboxetine	Female	2	01. APPARENT SADNESS	4	4	4	4	4	4	4
									02. REPORTED SADNESS	4	4	4	4	4	4	
									03. INNER TENSION	4	4	4	4	4	4	
									04. REDUCED SLEEP	5	5	5	5	5	5	
									05. REDUCED APPETITE	2	2	2	2	2	2	
									06. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	
									07. LASSITUDE	2	2	2	2	2	2	
									08. INABILITY TO FEEL	3	3	3	3	3	3	
09. PESSIMISTIC THOUGHTS	2	2	2	2					2	2						
10. SUICIDAL THOUGHTS	2	2	2	2					2	2						
11. Total score	30	30	30	30					30	30						
13	335	Placebo	Male	2	01. APPARENT SADNESS	2	2	3	2	2	2	2				
					02. REPORTED SADNESS	4	3	3	3	3	3					
					03. INNER TENSION	4	3	3	3	3	3					
					04. REDUCED SLEEP	2	2	3	4	4	4					
					05. REDUCED APPETITE	2	0	0	0	0	0					
					06. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2					
					07. LASSITUDE	3	3	3	3	3	3					
					08. INABILITY TO FEEL	2	2	2	2	2	2					
					09. PESSIMISTIC THOUGHTS	2	2	2	2	2	2					
					10. SUICIDAL THOUGHTS	2	1	1	2	2	1					
					11. Total score	25	21	22	22	22	19					
86	336	Imipramine	Female	2	01. APPARENT SADNESS	6	6	6	6	6	6	6				
					02. REPORTED SADNESS	6	6	6	6	6	6					
					03. INNER TENSION	4	4	4	4	4	4					
					04. REDUCED SLEEP	4	4	4	4	4	4					
					05. REDUCED APPETITE	0	0	0	0	0	0					
					06. CONCENTRATIONS DIFFICULTIES	4	4	4	4	4	4					
					07. LASSITUDE	4	4	4	4	4	4					
					08. INABILITY TO FEEL	5	4	4	4	4	4					
					09. PESSIMISTIC THOUGHTS	3	3	3	3	3	3					
					10. SUICIDAL THOUGHTS	2	2	2	2	2	2					
					11. Total score	38	39	39	39	39	39					
337	Reboxetine	Female	2	01. APPARENT SADNESS	2	3	3	3	3	4	4	3				
				02. REPORTED SADNESS	5	5	4	4	5	4	4					
				03. INNER TENSION	2	2	2	2	3	3	3					
				04. REDUCED SLEEP	4	4	4	4	4	4	4					
				05. REDUCED APPETITE	2	2	2	2	2	2	0					
				06. CONCENTRATIONS DIFFICULTIES	3	3	3	3	3	3	3					
				07. LASSITUDE	3	3	3	3	3	3	2					

9550082

78

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS 38D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
11	337	Reboxetine	Female	2	08. INABILITY TO FEEL	4	4	3	3	3	3	3	3				
					09. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2					
					10. SUICIDAL THOUGHTS	2	2	2	2	3	3	3					
					11. Total score	29	30	27	27	31	29	27					
					338	Imipramine	Male	2	01. APPARENT SADNESS	4	4						
									02. REPORTED SADNESS	4	4						
									03. INNER TENSION	3	3						
									04. REDUCED SLEEP	4	4						
									05. REDUCED APPETITE	2	2						
									06. CONCENTRATIONS DIFFICULTIES	2	3						
									07. LASSITUDE	4	4						
08. INABILITY TO FEEL	4	4															
09. PESSIMISTIC THOUGHTS	3	3															
10. SUICIDAL THOUGHTS	3	3															
11. Total score	33	34															
12	367	Reboxetine	Female	2	01. APPARENT SADNESS	4	2	2	0	0	0	0	0				
					02. REPORTED SADNESS	3	2	1	0	0	0	0					
					03. INNER TENSION	3	1	2	2	1	0	0					
					04. REDUCED SLEEP	5	3	3	2	2	2	2					
					05. REDUCED APPETITE	3	0	1	0	0	0	0					
					06. CONCENTRATIONS DIFFICULTIES	4	1	2	2	1	0	1					
					07. LASSITUDE	4	4	3	3	0	0	0					
					08. INABILITY TO FEEL	4	3	3	1	0	0	0					
					09. PESSIMISTIC THOUGHTS	2	2	1	1	1	0	0					
					10. SUICIDAL THOUGHTS	1	1	1	1	1	0	0					
					11. Total score	33	18	19	9	4	2	3					
368	368	Placebo	Female	2	01. APPARENT SADNESS	4	3	3	2	2	2	2	1				
					02. REPORTED SADNESS	4	3	4	2	2	2	2					
					03. INNER TENSION	2	3	2	1	2	1	1					
					04. REDUCED SLEEP	3	4	2	2	1	2	3					
					05. REDUCED APPETITE	2	2	1	0	1	0	1					
					06. CONCENTRATIONS DIFFICULTIES	4	4	4	1	2	2	1					
					07. LASSITUDE	4	4	4	4	4	4	4					
					08. INABILITY TO FEEL	4	4	3	4	3	2	2					
					09. PESSIMISTIC THOUGHTS	1	2	2	1	1	1	1					
					10. SUICIDAL THOUGHTS	1	1	1	1	1	0	0					
					11. Total score	29	30	26	18	19	16	16					
369	369	Imipramine	Female	2	01. APPARENT SADNESS	2	0	2	4								
					02. REPORTED SADNESS	4	1	2	5								
					03. INNER TENSION	5	1	3	6								
					04. REDUCED SLEEP	4	1	3	2								
					05. REDUCED APPETITE	2	0	0	1								
					06. CONCENTRATIONS DIFFICULTIES	3	1	1	3								

1387

9550082

79

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0
MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
12	369	Imipramine	Female	2	07.LASSITUDE	4	1	2	5							
					08.INABILITY TO FEEL	5	1	3	5							
					09.PESSIMISTIC THOUGHTS	4	1	2	3							
					10.SUICIDAL THOUGHTS	4	0	1	5							
					11.Total score	37	7	19	39							
					370	Placebo	Male	2	01.APPARENT SADNESS	5	3	4	5			
									02.REPORTED SADNESS	4	3	4	4			
									03.INNER TENSION	2	2	2	3			
									04.REDUCED SLEEP	3	2	3	3			
									05.REDUCED APPETITE	3	2	3	4			
									06.CONCENTRATIONS DIFFICULTIES	3	1	5	3			
07.LASSITUDE	3	2	4	4												
08.INABILITY TO FEEL	4	3	4	4												
09.PESSIMISTIC THOUGHTS	5	2	2	4												
10.SUICIDAL THOUGHTS	3	1	2	3												
11.Total score	35	21	33	37												
371	Imipramine	Female	2	01.APPARENT SADNESS	4	1										
				02.REPORTED SADNESS	4	2										
				03.INNER TENSION	4	2										
				04.REDUCED SLEEP	4	2										
				05.REDUCED APPETITE	0	1										
				06.CONCENTRATIONS DIFFICULTIES	3	2										
				07.LASSITUDE	4	2										
				08.INABILITY TO FEEL	4	1										
				09.PESSIMISTIC THOUGHTS	2	2										
				10.SUICIDAL THOUGHTS	1	1										
				11.Total score	29	16										
372	Reboxetine	Male	2	01.APPARENT SADNESS	5	4	2	1	0	0	3					
				02.REPORTED SADNESS	4	4	1	0	1	0	3					
				03.INNER TENSION	5	4	2	2	2	2	2					
				04.REDUCED SLEEP	4	2	0	0	0	2	2					
				05.REDUCED APPETITE	4	2	0	0	0	0	2					
				06.CONCENTRATIONS DIFFICULTIES	4	2	1	1	1	0	2					
				07.LASSITUDE	3	3	2	0	0	2	2					
				08.INABILITY TO FEEL	4	2	2	0	0	0	2					
				09.PESSIMISTIC THOUGHTS	4	5	2	0	0	2	2					
				10.SUICIDAL THOUGHTS	4	4	1	0	1	0	2					
				11.Total score	41	32	15	4	5	4	22					
373	Reboxetine	Male	2	01.APPARENT SADNESS	4	1	4	1	0	0	0					
				02.REPORTED SADNESS	4	1	4	1	1	1	0					
				03.INNER TENSION	4	2	3	2	0	1	1					
				04.REDUCED SLEEP	3	3	5	4	2	3	2					
				05.REDUCED APPETITE	2	0	4	0	0	1	0					

1388

9550082

80

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0
MONTGOMERY ASBERG DEPRESSION RATING SCALE

Center	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
12	373	Reboxetine	Male	2	06. CONCENTRATIONS DIFFICULTIES	0	1	5	3	3	1	0					
					07. LASSITUDE	2	0	4	4	3	0	0					
					08. INABILITY TO FEEL	2	1	4	3	3	0	0					
					09. PESSIMISTIC THOUGHTS	2	2	3	3	1	0						
					10. SUICIDAL THOUGHTS	4	2	4	2	1	0						
					11. Total score	27	13	40	23	19	10	4					
					374	Placebo	Female	2	01. APPARENT SADNESS	3	3	2	3	2	2		
									02. REPORTED SADNESS	4	3	1	2	1			
									03. INNER TENSION	2	4	2	3	2			
									04. REDUCED SLEEP	0	0	0	0	4			
									05. REDUCED APPETITE	2	1	0	0	0			
06. CONCENTRATIONS DIFFICULTIES	2	4	1	2					2								
07. LASSITUDE	4	4	2	2					2								
08. INABILITY TO FEEL	5	2	2	3					2								
09. PESSIMISTIC THOUGHTS	2	1	1	2					1								
10. SUICIDAL THOUGHTS	2	1	1	1					0								
11. Total score	26	22	12	18					16								
13	375	Imipramine	Male	2	01. APPARENT SADNESS	4											
					02. REPORTED SADNESS	5											
					03. INNER TENSION	4											
					04. REDUCED SLEEP	3											
					05. REDUCED APPETITE	2											
					06. CONCENTRATIONS DIFFICULTIES	3											
					07. LASSITUDE	2											
					08. INABILITY TO FEEL	3											
					09. PESSIMISTIC THOUGHTS	5											
					10. SUICIDAL THOUGHTS	4											
					11. Total score	35											
13	13	Placebo	Male	1	01. REPORTED SADNESS	1	1	0	2	1	2	2					
					02. INNER TENSION	2	1	1	2	2	1	2					
					03. APPARENT SADNESS	1	1	1	1	1	2	2					
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1					
					05. INERTIA	1	2	1	1	1	2	1					
					06. INABILITY TO FEEL	1	1	1	1	1	2	2					
					07. PESSIMISTIC THOUGHTS	1	1	1	2	1	2	2					
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	2	2	2	2					
					09. REDUCED SLEEP	1	1	1	1	1	1	1					
					10. REDUCED APPETITE	1	1	0	0	0	1	1					
					11. Total score	11	11	8	13	11	16	16					
14	14	Placebo	Male	1	01. REPORTED SADNESS	2	1	2	1	0	1	0					
					02. INNER TENSION	2	1	2	1	1	1	1					
					03. APPARENT SADNESS	2	0	2	2	0	1	1					
					04. SUICIDAL THOUGHTS	1	1	2	1	0	0	1					

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31

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 33.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Deafine Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	
13	14	Male	1	05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	1	1	1	2	2	1	1	1	
15	15	Female	1	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2	1	1	1	1	2	2	2	2
16	16	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL 09. PESSIMISTIC THOUGHTS 10. SUICIDAL THOUGHTS 11. Total score	2	3	2	2	0	1	2	1	2
17	17	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION 04. REDUCED SLEEP 05. REDUCED APPETITE 06. CONCENTRATIONS DIFFICULTIES 07. LASSITUDE 08. INABILITY TO FEEL 09. PESSIMISTIC THOUGHTS 10. SUICIDAL THOUGHTS 11. Total score	2	2	2	2	2	2	2	2	2
18	18	Male	2	01. APPARENT SADNESS 02. REPORTED SADNESS 03. INNER TENSION	2	2	2	2	2	2	2	2	2

1390

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
13	18	Reboxetine	Male	2	04. REDUCED SLEEP	1	1	1	0	1	0	2				
					05. REDUCED APPETITE	0	0	0	0	0	0					
					06. CONCENTRATIONS DIFFICULTIES	2	3	3	3	4	3					
					07. LASSITUDE	2	1	1	1	1	2					
					08. INABILITY TO FEEL	1	1	2	2	2	1					
					09. PESSIMISTIC THOUGHTS	1	1	1	1	1	0					
					10. SUICIDAL THOUGHTS	1	1	0	0	1	0					
					11. Total score	13	13	13	11	15	12					
					409	409	Reboxetine	Male	2	01. APPARENT SADNESS	2	3	2	2	2	2
										02. REPORTED SADNESS	1	2	1	2	2	1
										03. INNER TENSION	3	2	2	2	2	2
04. REDUCED SLEEP	0	3	3	2						2	1					
05. REDUCED APPETITE	2	2	2	2						2	2					
06. CONCENTRATIONS DIFFICULTIES	2	2	2	2						2	1					
07. LASSITUDE	1	1	1	1						1	2					
08. INABILITY TO FEEL	1	2	1	2						2	1					
09. PESSIMISTIC THOUGHTS	1	2	1	1						1	1					
10. SUICIDAL THOUGHTS	1	1	1	1						1	1					
11. Total score	14	18	16	17						14	14					
410	410	Placebo	Male	2	01. APPARENT SADNESS	3	3	4	3	2	3					
					02. REPORTED SADNESS	3	3	3	2	1	3					
					03. INNER TENSION	3	2	3	3	2	2					
					04. REDUCED SLEEP	2	2	2	2	0	2					
					05. REDUCED APPETITE	3	2	3	3	1	2					
					06. CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	2					
					07. LASSITUDE	2	2	3	3	2	2					
					08. INABILITY TO FEEL	2	2	2	2	2	2					
					09. PESSIMISTIC THOUGHTS	2	2	2	2	1	1					
					10. SUICIDAL THOUGHTS	1	1	2	1	1	1					
					11. Total score	24	22	26	22	14	20					
411	411	Imipramine	Female	2	01. APPARENT SADNESS	2	1	1	3	4	2					
					02. REPORTED SADNESS	3	1	1	3	3	1					
					03. INNER TENSION	2	1	1	3	3	2					
					04. REDUCED SLEEP	3	0	0	0	0	0					
					05. REDUCED APPETITE	2	1	0	1	0	0					
					06. CONCENTRATIONS DIFFICULTIES	2	2	1	3	3	2					
					07. LASSITUDE	2	1	1	2	2	2					
					08. INABILITY TO FEEL	2	1	0	1	2	1					
					09. PESSIMISTIC THOUGHTS	2	1	0	1	2	2					
					10. SUICIDAL THOUGHTS	2	1	1	1	1	1					
					11. Total score	22	11	6	19	20	14					
423	423	Placebo	Male	2	01. APPARENT SADNESS	2	2	3	2	2						
					02. REPORTED SADNESS	1	1	2	2	1						

13
39
1

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83

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centbro Patient	Treatment	Sex	Scale Type	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	
13	423	Male	2	Montgomery Asberg Depression Rating Scale								
				2	1	2	2	2	2	2	1	
				1	0	0	0	0	0	0	0	
				3	2	2	2	2	2	2	1	
				2	2	2	2	2	2	2	1	
				2	1	2	2	2	2	2	2	
				2	2	1	2	2	2	2	2	
				1	1	1	1	1	1	1	1	
				16	14	17	16				11	
14	19	Female	2	Montgomery Asberg Depression Rating Scale								
				6	6	6	3	4	5	4	5	
				6	6	6	4	4	4	4	4	
				4	5	5	3	2	3	3	3	
				5	4	4	4	4	4	4	5	
				4	5	5	2	3	4	4	4	
				6	6	6	3	4	4	4	4	
				5	5	5	3	4	4	4	4	
				5	5	4	2	2	2	2	3	
				3	2	2	2	2	2	2	2	
				3	2	2	2	2	2	2	2	
				47	48	30	30	30	39		39	
20		Female	2	Montgomery Asberg Depression Rating Scale								
				2	3	2	1	1	1	0	0	
				3	3	1	1	1	2	0	0	
				4	4	3	2	2	2	1	1	
				4	4	5	2	2	2	2	0	
				3	1	0	0	0	0	0	0	
				4	3	2	1	0	0	0	0	
				3	3	4	4	1	0	1	1	
				4	4	4	1	1	1	0	1	
				3	4	2	2	0	0	0	0	
				2	2	1	1	1	0	0	0	
				32	30	24	12	8	3	3	3	
21		Female	2	Montgomery Asberg Depression Rating Scale								
				4	4	2	4	3	3	3	3	
				4	4	2	4	3	4	3	4	
				3	3	2	3	3	3	3	3	
				5	4	1	3	3	3	3	3	
				4	4	0	2	0	0	0	0	
				4	3	2	3	3	3	2	2	
				4	4	2	2	2	2	3	3	
				4	4	2	2	2	2	2	3	
				1	1	2	3	4	2	2	2	
				2	1	1	4	4	3	2	2	
				35	27	17	31	24	25		25	
15	25	Female	1	Montgomery Asberg Depression Rating Scale								
				2	2	1	2	2	2	2	1	

13393

9550082

84

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	25	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	2	2	1	1	1
					02. INNER TENSION	1	1	1	1	1	1	
					03. APPARENT SADNESS	1	1	1	1	1	1	
					04. SUICIDAL THOUGHTS	2	2	2	2	2	2	
					05. INERTIA	2	2	2	2	2	2	
					06. INABILITY TO FEEL	1	1	1	1	1	1	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	
					09. REDUCED SLEEP	2	2	2	2	2	2	
					10. REDUCED APPETITE	1	1	1	1	1	1	
					11. Total score	16	17	14	16	13	12	
26	26	Placebo	Male	1	01. REPORTED SADNESS	2	2	1	1	2	1	1
					02. INNER TENSION	2	1	1	1	1	1	
					03. APPARENT SADNESS	1	1	1	1	2	1	
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1	
					05. INERTIA	2	1	2	1	1	1	
					06. INABILITY TO FEEL	2	2	2	1	2	2	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	0	1	1	
					09. REDUCED SLEEP	2	1	2	1	2	1	
					10. REDUCED APPETITE	1	1	1	1	0	0	
					11. Total score	15	13	13	9	13	10	
27	27	Imipramine	Female	1	01. REPORTED SADNESS	2	2	1	1	1	1	0
					02. INNER TENSION	2	2	1	1	1	1	
					03. APPARENT SADNESS	2	1	1	1	0	0	
					04. SUICIDAL THOUGHTS	1	1	1	1	0	0	
					05. INERTIA	1	2	2	1	0	1	
					06. INABILITY TO FEEL	2	2	1	0	1	0	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	0	
					08. CONCENTRATIONS DIFFICULTIES	2	2	1	0	0	1	
					09. REDUCED SLEEP	2	1	2	1	0	0	
					10. REDUCED APPETITE	1	0	0	0	0	0	
					11. Total score	16	14	11	7	4	3	
28	28	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	1	1	1	1	0
					02. INNER TENSION	1	1	1	1	1	1	
					03. APPARENT SADNESS	2	2	1	1	1	1	
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1	
					05. INERTIA	2	1	1	1	1	1	
					06. INABILITY TO FEEL	1	2	1	0	0	0	
					07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	
					08. CONCENTRATIONS DIFFICULTIES	1	1	1	0	1	1	
					09. REDUCED SLEEP	2	2	2	1	1	1	
					10. REDUCED APPETITE	0	0	0	0	0	0	
					11. Total score	13	13	10	7	7	8	

1393

9550082

85

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Center	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
15	29	Placebo	Male	1	01. REPORTED SADNESS	2	2	2	2	2	2	2	2
					02. INNER TENSION	2	2	2	2	2	2	2	2
					03. APPARENT SADNESS	1	1	1	1	1	1	1	
					04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1	
					05. INERTIA	2	2	2	2	2	2	2	
					06. INABILITY TO FEEL	1	1	1	1	1	1	1	
					07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2	
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	
					09. REDUCED SLEEP	2	1	1	1	1	1	1	
					10. REDUCED APPETITE	0	0	0	0	0	0	0	
					11. Total score	15	14	14	14	16			
30	Imipramine	Female	1	01. REPORTED SADNESS	2	2	2	2	1	1	1	0	
				02. INNER TENSION	2	1	1	1	1	1	0		
				03. APPARENT SADNESS	1	1	1	1	1	1	0		
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	0		
				05. INERTIA	1	1	1	1	1	1	1		
				06. INABILITY TO FEEL	2	2	2	2	1	1	1		
				07. PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1		
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1		
				09. REDUCED SLEEP	1	1	1	1	0	1	0		
				10. REDUCED APPETITE	0	0	0	0	0	0	0		
				11. Total score	14	13	12	7	10	5	5		
403	Imipramine	Female	1	01. REPORTED SADNESS	2	1	1	1	1	0	0	0	
				02. INNER TENSION	1	1	2	1	1	1	1		
				03. APPARENT SADNESS	2	1	1	1	1	0	0		
				04. SUICIDAL THOUGHTS	1	1	1	1	0	0	0		
				05. INERTIA	2	2	2	1	1	1	1		
				06. INABILITY TO FEEL	2	2	2	2	1	1	0		
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	0	0		
				08. CONCENTRATIONS DIFFICULTIES	2	1	1	1	0	0	1		
				09. REDUCED SLEEP	2	2	2	2	1	1	1		
				10. REDUCED APPETITE	1	0	0	0	0	0	0		
				11. Total score	16	12	12	7	5	4	4		
404	Reboxetine	Female	1	01. REPORTED SADNESS	2	2	2	2	2	2	2	2	
				02. INNER TENSION	1	2	2	2	2	2	2		
				03. APPARENT SADNESS	1	1	1	1	1	1	1		
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1		
				05. INERTIA	1	1	2	2	2	2	2		
				06. INABILITY TO FEEL	2	1	1	1	1	1	1		
				07. PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1		
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	2	2	2		
				09. REDUCED SLEEP	1	1	2	2	1	1	1		
				10. REDUCED APPETITE	1	1	0	0	0	0	1		
				11. Total score	15	14	15	15	15	15	16		

1394

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86

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012s/015
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
15	405	Placebo	Female	2	01. APPARENT SADNESS	4	3	5	2	1	1	1	0
					02. REPORTED SADNESS	5	4	4	1	1	1	0	
					03. INNER TENSION	3	3	3	2	1	1	1	
					04. REDUCED SLEEP	4	4	3	2	1	0	1	
					05. REDUCED APPETITE	2	2	2	1	0	0	0	
					06. CONCENTRATIONS DIFFICULTIES	3	3	3	2	2	1	1	
					07. LASSITUDE	4	4	4	3	2	2	1	
					08. INABILITY TO FEEL	4	4	4	3	2	1	1	
					09. PESSIMISTIC THOUGHTS	2	2	3	2	1	1	0	
					10. SUICIDAL THOUGHTS	1	1	1	1	0	0	0	
					11. Total score	32	30	29	18	10	8	4	
1305	406	Imipramine	Male	2	01. APPARENT SADNESS	4	3	3	2	2	2	2	2
					02. REPORTED SADNESS	4	4	3	2	2	2	2	
					03. INNER TENSION	3	3	3	2	2	2	2	
					04. REDUCED SLEEP	2	3	2	2	3	2	3	
					05. REDUCED APPETITE	2	2	2	1	1	0	0	
					06. CONCENTRATIONS DIFFICULTIES	3	3	2	3	2	1	1	
					07. LASSITUDE	4	4	4	3	2	1	1	
					08. INABILITY TO FEEL	4	4	4	3	2	1	1	
					09. PESSIMISTIC THOUGHTS	2	3	2	2	2	2	2	
					10. SUICIDAL THOUGHTS	2	2	2	1	1	1	1	
					11. Total score	31	31	26	20	18	15	16	
407	407	Reboxetine	Female	2	01. APPARENT SADNESS	4	3	3	2	2	2	2	2
					02. REPORTED SADNESS	4	3	3	3	2	2	2	
					03. INNER TENSION	3	3	3	3	3	2	2	
					04. REDUCED SLEEP	4	3	3	3	3	2	2	
					05. REDUCED APPETITE	3	2	2	2	2	1	1	
					06. CONCENTRATIONS DIFFICULTIES	3	3	3	3	2	2	3	
					07. LASSITUDE	4	4	4	3	3	1	1	
					08. INABILITY TO FEEL	4	4	4	4	3	2	1	
					09. PESSIMISTIC THOUGHTS	3	3	3	2	2	2	2	
					10. SUICIDAL THOUGHTS	3	3	3	2	2	0	0	
					11. Total score	35	31	29	27	24	16	16	
408	408	Placebo	Female	2	01. APPARENT SADNESS	4	4	4	2	2	2	2	2
					02. REPORTED SADNESS	5	4	4	2	2	2	1	
					03. INNER TENSION	4	4	4	2	3	2	1	
					04. REDUCED SLEEP	3	3	2	3	3	2	2	
					05. REDUCED APPETITE	2	3	2	0	0	0	0	
					06. CONCENTRATIONS DIFFICULTIES	4	3	3	2	2	1	2	
					07. LASSITUDE	5	5	5	2	2	1	1	
					08. INABILITY TO FEEL	4	4	4	1	1	1	1	
					09. PESSIMISTIC THOUGHTS	3	3	3	2	1	2	1	
					10. SUICIDAL THOUGHTS	2	2	3	1	1	1	0	

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 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale Type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	
15	408	Placebo	Female	2	11. Total score	36	34	35	15	17	14	12				
					01. APPARENT SADNESS	4	3	3	2	2	2	1	1			
					02. REPORTED SADNESS	4	4	3	2	2	2	1	1			
					03. INNER TENSION	3	3	2	2	2	2	2	2			
					04. REDUCED SLEEP	0	1	1	0	0	0	0	0			
					05. REDUCED APPETITE	3	3	2	2	2	2	2	2			
					06. CONCENTRATIONS DIFFICULTIES	4	4	4	4	3	3	2	2			
					07. LASSITUDE	3	3	4	3	3	3	1	0			
					08. INABILITY TO FEEL	3	4	4	3	3	3	1	0			
					09. PESSIMISTIC THOUGHTS	2	2	3	3	3	3	1	1			
					10. SUICIDAL THOUGHTS	2	2	1	1	1	1	1	1			
					11. Total score	29	29	27	23	22	15	7				
419	419	Placebo	Female	2	01. APPARENT SADNESS	4	3	4	4	2	2	2				
					02. REPORTED SADNESS	4	3	4	4	2	2	2	2			
					03. INNER TENSION	2	2	3	2	3	3	2	2			
					04. REDUCED SLEEP	4	3	3	3	3	2	2	2			
					05. REDUCED APPETITE	2	0	2	2	2	0	0	0			
					06. CONCENTRATIONS DIFFICULTIES	3	2	3	3	1	3	3	3			
					07. LASSITUDE	3	2	3	3	2	2	2	2			
					08. INABILITY TO FEEL	4	2	2	2	2	2	2	2			
					09. PESSIMISTIC THOUGHTS	2	1	2	3	1	2	2	2			
					10. SUICIDAL THOUGHTS	3	0	2	2	1	0	0	0			
					11. Total score	31	18	28	28	19	18	17				

1396

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
1	1	Imipramine	Female	01. FACIAL EXPRESSION	3	3	1	1	1	1	1	0
				02. BODY GESTURES	3	4	1	1	1	0	0	0
				03. LOOK	3	2	0	2	0	0	1	0
				04. OUTWARD APPEARANCE	2	3	1	0	0	0	0	0
				05. SPEECH	3	3	1	1	0	0	1	0
				06. VOICE	3	2	0	0	0	0	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	0	1	1	1	0
				08. CONTACTS, AFFECTIVE NEED	3	3	2	2	1	1	1	0
				09. ANGUISH, ANXIETY	3	3	2	2	1	1	1	1
				10. AGGRESSION, IRRITABILITY	0	1	1	1	0	0	0	0
				11. SELF-AGGRESSION	0	2	1	1	0	0	0	0
				12. GLOBAL EVALUATION	3	2	1	1	1	1	1	0
11. Total score	28	30	12	9	5	7	7	2				
2	2	Reboxetine	Male	01. FACIAL EXPRESSION	3	3	1	1	1	1	1	1
				02. BODY GESTURES	3	3	0	1	1	0	0	0
				03. LOOK	3	2	0	1	1	0	0	0
				04. OUTWARD APPEARANCE	1	2	1	1	1	1	1	1
				05. SPEECH	2	2	1	1	1	1	0	2
				06. VOICE	2	2	1	0	1	0	0	1
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	0	0	0	0
				08. CONTACTS, AFFECTIVE NEED	2	3	1	1	1	1	1	1
				09. ANGUISH, ANXIETY	3	1	1	1	1	0	0	1
				10. AGGRESSION, IRRITABILITY	1	0	0	0	0	0	0	0
				11. SELF-AGGRESSION	2	3	0	0	0	0	0	0
				12. GLOBAL EVALUATION	2	2	2	2	1	1	1	1
11. Total score	26	25	10	7	10	4	4	8				
3	3	Imipramine	Male	01. FACIAL EXPRESSION	2	1	1	1	1	1	1	
				02. BODY GESTURES	1	0	1	1	1	1	1	
				03. LOOK	1	1	1	1	1	0	0	
				04. OUTWARD APPEARANCE	0	1	1	1	1	0	0	
				05. SPEECH	1	1	1	1	1	1	0	
				06. VOICE	1	0	0	1	0	0	1	
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	0	1	1	0	0	
				08. CONTACTS, AFFECTIVE NEED	3	1	1	2	1	0	0	
				09. ANGUISH, ANXIETY	2	1	1	2	1	1	0	
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0	
				11. SELF-AGGRESSION	0	0	0	0	0	0	0	
				12. GLOBAL EVALUATION	0	1	1	1	1	1	1	
11. Total score	15	8	8	12	7	5	4					
4	4	Placebo	Male	01. FACIAL EXPRESSION	1	1	0	0	0	0	0	
				02. BODY GESTURES	1	1	0	0	0	0	0	
				03. LOOK	0	1	0	0	0	0	0	
				04. OUTWARD APPEARANCE	1	1	0	0	0	0	0	
				05. SPEECH	2	0	1	1	0	0	0	
				06. VOICE	0	0	0	0	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	1	0	0	1	0	0	1	

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2

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PHARMACIA CMS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
1	4	Placebo	Male	08. CONTACTS, AFFECTIVE NEED	2	1	1	1	1	1	1				
				09. ANGUISH, ANXIETY	1	2	1	1	1	0	0	0			
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0	0			
				11. SELF-AGGRESSION	3	0	1	1	1	0	0	0			
				12. GLOBAL EVALUATION	1	1	0	0	0	0	0	0			
				11..Total score	13	8	5	5	2	2	2	2			
				5	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	1	1	1	1	1
							02. BODY GESTURES	1	1	1	1	1	1	1	1
							03. LOOK	1	1	1	1	1	1	1	1
							04. OUTWARD APPEARANCE	1	0	0	0	0	0	0	0
							05. SPEECH	2	2	2	2	2	2	2	2
							06. VOICE	1	1	1	1	1	1	1	1
							07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	1
							08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1	1
09. ANGUISH, ANXIETY	3	2	2				2	2	2	2	2				
10. AGGRESSION, IRRITABILITY	1	1	1				1	1	1	1	1				
11. SELF-AGGRESSION	0	1	1				1	1	1	1	1				
12. GLOBAL EVALUATION	1	1	2				2	2	2	2	2				
11..Total score	15	14	14				14	14	14	14	14				
6	Placebo	Female	01. FACIAL EXPRESSION				2	1	1	1	1	1	1	1	
			02. BODY GESTURES	2	2	2	2	2	2	2	2				
			03. LOOK	1	2	1	1	1	1	1	1				
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	1				
			05. SPEECH	1	1	1	1	1	1	1	1				
			06. VOICE	1	0	1	1	1	1	1	1				
			07. ADAPTABILITY, SUGGESTIBILITY	1	0	0	1	0	0	0	0				
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1	1				
			09. ANGUISH, ANXIETY	2	2	2	2	2	2	2	2				
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1				
			11. SELF-AGGRESSION	0	0	0	0	0	0	0	0				
			12. GLOBAL EVALUATION	1	0	1	1	1	1	1	1				
			11..Total score	14	11	12	11	7	4	6					
			7	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	1	1	1	1	1	
02. BODY GESTURES	1	0				1	0	0	0	0					
03. LOOK	2	1				1	0	0	0	0					
04. OUTWARD APPEARANCE	1	1				1	0	0	0	0					
05. SPEECH	1	1				1	0	0	0	0					
06. VOICE	1	1				1	0	0	0	0					
07. ADAPTABILITY, SUGGESTIBILITY	1	0				0	0	0	0	0					
08. CONTACTS, AFFECTIVE NEED	2	1				0	0	0	0	0					
09. ANGUISH, ANXIETY	2	1				0	0	0	0	0					
10. AGGRESSION, IRRITABILITY	1	1				1	1	1	1	1					
11. SELF-AGGRESSION	0	0				0	0	0	0	0					
12. GLOBAL EVALUATION	1	0				1	1	1	1	1					
11..Total score	14	8				6	2	3	3	2					

1398

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3

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	8	Placebo	Male	01.FACIAL EXPRESSION	1	1	1	1	0	0	0
				02.BODY GESTURES	1	0	0	0	0	0	
				03.LOOK	1	0	1	0	0	0	
				04.OUTWARD APPEARANCE	2	0	1	0	0	0	
				05.SPEECH	0	0	0	0	0	0	
				06.VOICE	0	0	0	0	0	0	
				07.ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	
				08.CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	
				09.ANGUISH, ANXIETY	0	0	0	1	1	1	
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0	
				11.SELF-AGGRESSION	0	0	0	0	0	0	
				12.GLOBAL EVALUATION	9	4	6	4	4	2	
11.Total score											
9		Reboxetine	Female	01.FACIAL EXPRESSION	1	1	1	1	1	1	0
				02.BODY GESTURES	1	1	1	1	1	1	
				03.LOOK	1	1	1	1	1	1	
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	
				05.SPEECH	1	1	1	1	1	1	
				06.VOICE	1	1	1	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	2	1	
				09.ANGUISH, ANXIETY	1	1	1	1	1	1	
				10.AGRESSION, IRRITABILITY	0	1	1	1	1	1	
				11.SELF-AGGRESSION	0	0	0	0	0	0	
				12.GLOBAL EVALUATION	10	11	11	11	11	5	
11.Total score											
10		Placebo	Male	01.FACIAL EXPRESSION	2	1	1	1	1	1	1
				02.BODY GESTURES	1	1	1	1	1	1	
				03.LOOK	1	1	1	1	1	1	
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	
				05.SPEECH	1	1	1	1	1	1	
				06.VOICE	1	1	1	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	1	0	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	
				09.ANGUISH, ANXIETY	1	1	1	1	1	1	
				10.AGRESSION, IRRITABILITY	0	1	0	1	1	1	
				11.SELF-AGGRESSION	0	0	0	0	0	0	
				12.GLOBAL EVALUATION	2	1	1	1	1	1	
11.Total score	12	10	10	11	11	11					
11		Imipramine	Female	01.FACIAL EXPRESSION	1						
				02.BODY GESTURES	1						
				03.LOOK	1						
				04.OUTWARD APPEARANCE	1						
				05.SPEECH	1						

1399

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4

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
1	11	Imipramine	Female	06.VOICE	1									
				07.ADAPTABILITY, SUGGESTIBILITY	1									
				08.CONTACTS, AFFECTIVE NEED	1									
				09.ANGUISH, ANXIETY	1									
				10.AGRESSION, IRRITABILITY	0									
				11.SELF-AGGRESSION	0									
				12.GLOBAL EVALUATION	1									
				11.Total score	10									
				01.FACIAL EXPRESSION	1	1	1	1	1	1	1	1	1	1
				02.BODY GESTURES	1	1	1	1	1	1	1	1	1	1
				03.LOOK	1	1	1	1	1	1	1	1	1	1
04.OUTWARD APPEARANCE	1	1	1	1	1	1	1	1	1	1				
05.SPEECH	1	1	1	1	1	1	1	1	1	1				
06.VOICE	1	1	1	1	1	1	1	1	1	1				
07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	1	1	1				
08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1	1	1	1				
09.ANGUISH, ANXIETY	1	1	1	1	1	1	1	1	1	1				
10.AGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1	1	1				
11.SELF-AGGRESSION	0	1	0	0	0	0	0	0	0	0				
12.GLOBAL EVALUATION	1	1	1	1	1	1	1	1	1	1				
11.Total score	11	11	6	7	3	3	3	3	3	3	2			
412		Reboxetine	Male	01.FACIAL EXPRESSION	1	1	1	1	1	1	1	1		
				02.BODY GESTURES	1	1	1	1	1	1	1	1		
				03.LOOK	1	1	1	1	1	1	1			
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	1			
				05.SPEECH	1	1	1	1	1	1	1			
				06.VOICE	1	1	1	1	1	1	1			
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1			
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1			
				09.ANGUISH, ANXIETY	1	1	1	1	1	1	1			
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	1	1			
				11.SELF-AGGRESSION	1	1	1	1	1	1	1			
12.GLOBAL EVALUATION	1	1	1	1	1	1	1							
11.Total score	12	8	8	4	11	4	4	2						
413		Placebo	Male	01.FACIAL EXPRESSION	1	1	1	1	1	1	1			
				02.BODY GESTURES	1	1	1	1	1	1	1			
				03.LOOK	1	1	1	1	1	1				
				04.OUTWARD APPEARANCE	1	1	1	1	1	1				
				05.SPEECH	1	1	1	1	1	1				
				06.VOICE	1	1	1	1	1	1				
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1				
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1				
				09.ANGUISH, ANXIETY	1	1	1	1	1	1				
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	1				
				11.SELF-AGGRESSION	0	0	0	0	0	0				
12.GLOBAL EVALUATION	1	1	1	1	1	1								

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1400

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5

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PHARMACIA CNS R2D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	413	Placebo	Male	11.Total score	11	11		11		8	10
	414	Imipramine	Female	01.FACIAL EXPRESSION	1	2	2				
				02.BODY GESTURES	1	2	2				
				03.LOOK	1	2	1				
				04.OUTWARD APPEARANCE	1	1	2				
				05.SPEECH	1	2	2				
				06.VOICE	1	1	2				
				07.ADAPTABILITY, SUGGESTIBILITY	1	2	2				
				08.CONTACTS, AFFECTIVE NEED	1	1	2				
				09.ANGUISH, ANXIETY	2	2	2				
				10.AGRESSION, IRRITABILITY	1	0	0				
				11.SELF-AGGRESSION	0	0	0				
				12.GLOBAL EVALUATION	1	1	2				
				11.Total score	12	16	19				
	415	Imipramine	Male	01.FACIAL EXPRESSION	1	1	1	0	1	0	0
				02.BODY GESTURES	0	0	0	1	0	0	0
				03.LOOK	0	0	1	0	0	0	0
				04.OUTWARD APPEARANCE	1	1	0	1	0	0	0
				05.SPEECH	1	1	1	1	1	1	1
				06.VOICE	1	1	1	0	1	1	0
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	0	1	0
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	0
				09.ANGUISH, ANXIETY	1	1	1	2	1	0	0
				10.AGRESSION, IRRITABILITY	0	0	0	1	0	0	0
				11.SELF-AGGRESSION	1	0	0	0	0	0	0
				12.GLOBAL EVALUATION	1	1	1	1	0	0	0
				11.Total score	9	8	8	9	5	3	1
	416	Reboxetine	Female	01.FACIAL EXPRESSION	1	1	1				
				02.BODY GESTURES	1	1	1				
				03.LOOK	1	1	1				
				04.OUTWARD APPEARANCE	2	1	1				
				05.SPEECH	1	1	1				
				06.VOICE	1	1	1				
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1				
				08.CONTACTS, AFFECTIVE NEED	1	1	1				
				09.ANGUISH, ANXIETY	1	1	2				
				10.AGRESSION, IRRITABILITY	1	1	0				
				11.SELF-AGGRESSION	0	0	0				
				12.GLOBAL EVALUATION	1	1	1				
				11.Total score	12	11	11				
	421	Imipramine	Male	01.FACIAL EXPRESSION	2	2	1	1	1	0	0
				02.BODY GESTURES	2	2	1	1	1	0	0
				03.LOOK	1	1	1	0	0	1	0
				04.OUTWARD APPEARANCE	2	1	1	0	0	1	0

1401

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6

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
1	421	Imipramine	Male	05. SPEECH	1	1	1	1	0	0	1	1
				06. VOICE	1	1	0	1	0	0	0	1
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	1	0
				08. CONTACTS, AFFECTIVE NEED	2	2	0	1	1	1	0	
				09. ANGUISH, ANXIETY	1	1	1	0	1	1	1	
				10. AGGRESSION, IRRITABILITY	0	0	1	0	0	0	0	
				11. SELF-AGGRESSION	0	0	0	0	0	0	0	
				12. GLOBAL EVALUATION	1	1	1	1	1	1	0	
				11.Total score	15	13	9	7	7	7	3	
				01. FACIAL EXPRESSION	2	1	1	0	0	1	0	
				02. BODY GESTURES	2	1	1	0	1	0	0	
03. LOOK	1	1	1	1	1	1	0					
04. OUTWARD APPEARANCE	1	1	0	0	1	1	0					
05. SPEECH	2	1	1	0	1	1	0					
06. VOICE	1	1	0	1	0	1	0					
07. ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	0	0	0					
08. CONTACTS, AFFECTIVE NEED	1	1	1	0	0	1	0					
09. ANGUISH, ANXIETY	1	1	1	1	1	1	1					
10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0					
11. SELF-AGGRESSION	0	0	0	0	0	0	0					
12. GLOBAL EVALUATION	1	1	1	1	1	1	1					
11.Total score	13	10	6	3	6	8	1					
2/1	49	Placebo	Female	01. FACIAL EXPRESSION	2	2	0	0	0	0	0	0
				02. BODY GESTURES	1	1	0	0	0	0	0	
				03. LOOK	1	1	0	0	0	0	0	
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0	
				05. SPEECH	1	1	0	0	0	0	0	
				06. VOICE	1	0	0	0	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	0	0	0	
				08. CONTACTS, AFFECTIVE NEED	2	2	1	0	0	0	0	
				09. ANGUISH, ANXIETY	2	2	1	0	0	0	0	
				10. AGGRESSION, IRRITABILITY	1	0	0	0	0	0	0	
				11. SELF-AGGRESSION	1	0	0	0	0	0	0	
12. GLOBAL EVALUATION	1	1	0	0	0	0	0					
11.Total score	14	10	1	0	0	0	0					
50	Reboxetine	Female	Female	01. FACIAL EXPRESSION	0	0	0	0	0	0	0	
				02. BODY GESTURES	0	0	0	0	0	0	0	
				03. LOOK	0	0	0	0	0	0	0	
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0	
				05. SPEECH	1	0	0	0	0	0	0	
				06. VOICE	1	0	0	0	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	0	0	1	0	0	0	0	
				08. CONTACTS, AFFECTIVE NEED	1	0	0	0	0	0	0	
				09. ANGUISH, ANXIETY	1	0	0	0	0	0	0	
				10. AGGRESSION, IRRITABILITY	1	0	0	0	0	0	0	
				11. SELF-AGGRESSION	0	0	0	0	0	0	0	

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7

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PHARMACIA CMS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 14.0

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/1	50	Reboxetine	Female	12.GLOBAL EVALUATION 11.Total score	1 6	1 3	1 1	0 0	0 0	0 0	0 0
	51	Imipramine	Female	01.FACIAL EXPRESSION 02.BODY GESTURES 03.LOOK 04.OUTWARD APPEARANCE 05.SPEECH 06.VOICE 07.ADAPTABILITY, SUGGESTIBILITY 08.CONTACTS, AFFECTIVE NEED 09.ANGUISH, ANXIETY 10.AGRESSION, IRRITABILITY 11.SELF-AGGRESSION 12.GLOBAL EVALUATION 11.Total score	0 0 0 2 2 1 1 3 3 3 1 12	0 0 0 2 2 1 1 3 2 1 1 11	0 0 0 1 1 0 0 2 2 1 1 7	0 0 0 0 0 0 0 1 0 0 0 1	0 0 0 0 0 0 0 2 0 0 0 2	0 0 0 0 0 0 0 0 0 0 2	
2/2	43	Imipramine	Female	01.FACIAL EXPRESSION 02.BODY GESTURES 03.LOOK 04.OUTWARD APPEARANCE 05.SPEECH 06.VOICE 07.ADAPTABILITY, SUGGESTIBILITY 08.CONTACTS, AFFECTIVE NEED 09.ANGUISH, ANXIETY 10.AGRESSION, IRRITABILITY 11.SELF-AGGRESSION 12.GLOBAL EVALUATION 11.Total score	2 2 2 0 2 2 0 2 2 2 1 2 18	0 0 1 0 1 1 0 0 1 1 0 0 5	1 1 2 0 1 1 2 1 1 1 0 1 12	1 1 0 0 0 0 0 0 0 0 0 0 2	1 0 0 0 0 0 0 0 0 0 0 0 2	1 0 0 0 0 0 0 0 0 0 0 0 3	
	44	Imipramine	Female	01.FACIAL EXPRESSION 02.BODY GESTURES 03.LOOK 04.OUTWARD APPEARANCE 05.SPEECH 06.VOICE 07.ADAPTABILITY, SUGGESTIBILITY 08.CONTACTS, AFFECTIVE NEED 09.ANGUISH, ANXIETY 10.AGRESSION, IRRITABILITY 11.SELF-AGGRESSION 12.GLOBAL EVALUATION 11.Total score	1 0 0 2 2 1 1 1 2 1 1 1 11	0 0 0 0 2 1 0 0 3 1 1 1 8	0 0 0 1 1 0 0 1 2 1 1 1 6	1 0 0 0 1 0 0 1 1 1 1 7	0 0 0 0 0 0 0 0 1 0 0 0 3	0 1 0 0 0 0 0 0 1 1 0 0 7	
	45	Reboxetine	Female	01.FACIAL EXPRESSION 02.BODY GESTURES 03.LOOK	1 1 0	1 1 0	1 0 0	0 0 1	1 0 0	0 0 0	0 0 0

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8

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
2/2	45	Reboxetine	Female	04. OUTWARD APPEARANCE	0	0	0	1	0	0	1				
				05. SPEECH	1	1	0	1	0	1	0				
				06. VOICE	1	1	0	0	1	1					
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	1	1					
				08. CONTACTS, AFFECTIVE NEED	1	1	0	0	1	1					
				09. ANGUISH, ANXIETY	3	0	1	0	1	0					
				10. AGGRESSION, IRRITABILITY	2	2	0	1	1	1					
				11. SELF-AGGRESSION	1	1	0	1	1	1					
				12. GLOBAL EVALUATION	2	1	0	0	1	0					
				11.Total score	14	9	3	5	8	7					
				46	Placebo	Female	01. FACIAL EXPRESSION	1	1	0	0	0	0	0	0
							02. BODY GESTURES	1	1	0	0	0	0		
							03. LOOK	1	1	0	0	0	0		
04. OUTWARD APPEARANCE	0	0	0				0	0	0						
05. SPEECH	0	0	0				0	0	0						
06. VOICE	1	1	0				0	0	0						
07. ADAPTABILITY, SUGGESTIBILITY	1	1	0				0	0	0						
08. CONTACTS, AFFECTIVE NEED	1	2	0				0	0	0						
09. ANGUISH, ANXIETY	2	0	0				0	1	1						
10. AGGRESSION, IRRITABILITY	2	2	1				1	1	1						
11. SELF-AGGRESSION	2	1	1				1	1	1						
12. GLOBAL EVALUATION	1	1	0				0	0	0						
11.Total score	13	11	2				2	3	3						
47	Placebo	Female	01. FACIAL EXPRESSION	1	2	1	1	1	2	1	1				
			02. BODY GESTURES	2	0	1	1	1	2	1					
			03. LOOK	2	2	1	0	0	2	1					
			04. OUTWARD APPEARANCE	1	0	0	0	0	0	1					
			05. SPEECH	3	2	1	1	1	2	1					
			06. VOICE	2	2	1	0	2	2	1					
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	0	1	3	1	1					
			08. CONTACTS, AFFECTIVE NEED	3	2	1	1	2	2	1					
			09. ANGUISH, ANXIETY	3	3	1	1	2	2	1					
			10. AGGRESSION, IRRITABILITY	1	2	1	1	2	2	1					
			11. SELF-AGGRESSION	2	2	1	1	2	1	1					
			12. GLOBAL EVALUATION	1	1	1	0	1	1	1					
			11.Total score	23	19	11	9	22	13	16					
48	Reboxetine	Female	01. FACIAL EXPRESSION	3	1	2	1	1	2	1	1				
			02. BODY GESTURES	2	2	2	1	1	1	1					
			03. LOOK	3	1	1	1	1	1	1					
			04. OUTWARD APPEARANCE	2	1	2	0	0	0	0					
			05. SPEECH	2	1	2	1	2	1	2					
			06. VOICE	2	1	2	1	2	1	2					
			07. ADAPTABILITY, SUGGESTIBILITY	3	2	2	0	0	0	1					
			08. CONTACTS, AFFECTIVE NEED	3	3	1	0	1	2	1					
			09. ANGUISH, ANXIETY	3	3	2	1	1	1	1					
			10. AGGRESSION, IRRITABILITY	1	3	3	1	0	2	2					
			11. SELF-AGGRESSION	4	3	3	1	1	1	1					
			12. GLOBAL EVALUATION	2	2	2	1	1	1	1					
			11.Total score	24	21	21	11	11	11	11					

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9

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/2	48	Reboxetine	Female	11.SELF-AGGRESSION	2	2	1	0	1	1	1
				12.GLOBAL EVALUATION	2	2	2	1	1	1	
				11.Total score	30	20	20	8	11	13	
2/3	36/A	Imipramine	Male	01.FACIAL EXPRESSION	3	3	1	0	0	0	0
				02.BODY GESTURES	3	3	1	0	0	0	
				03.LOOK	3	3	1	0	0	0	
				04.OUTWARD APPEARANCE	2	2	1	0	0	0	
				05.SPEECH	2	2	1	0	0	0	
				06.VOICE	2	2	1	1	0	0	
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	0	
				08.CONTACTS, AFFECTIVE NEED	2	2	1	1	0	0	
				09.ANGUISH, ANXIETY	2	2	2	2	1	0	
				10.AGRESSION, IRRITABILITY	2	2	3	1	1	0	
				11.SELF-AGGRESSION	1	1	0	0	0	0	
				12.GLOBAL EVALUATION	3	3	1	0	0	0	
11.Total score	27	27	14	6	5	1					
37	37	Reboxetine	Female	01.FACIAL EXPRESSION	3	3	3	1	1	1	1
				02.BODY GESTURES	3	3	3	2	2	2	
				03.LOOK	2	2	2	1	1	1	
				04.OUTWARD APPEARANCE	2	2	2	1	1	1	
				05.SPEECH	2	2	2	1	1	1	
				06.VOICE	2	2	2	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	3	2	2	1	
				08.CONTACTS, AFFECTIVE NEED	3	3	3	2	2	2	
				09.ANGUISH, ANXIETY	2	2	3	2	2	2	
				10.AGRESSION, IRRITABILITY	2	2	2	1	1	1	
				11.SELF-AGGRESSION	1	1	1	1	1	1	
				12.GLOBAL EVALUATION	3	3	3	2	2	2	
11.Total score	28	29	29	17	17	16					
38	38	Placebo	Male	01.FACIAL EXPRESSION	1	2	2	1	1	1	1
				02.BODY GESTURES	3	2	2	2	2	1	
				03.LOOK	3	2	2	2	2	0	
				04.OUTWARD APPEARANCE	2	2	2	2	1	1	
				05.SPEECH	3	3	3	2	1	0	
				06.VOICE	2	2	3	2	1	0	
				07.ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	1	0	
				08.CONTACTS, AFFECTIVE NEED	3	3	3	3	1	1	
				09.ANGUISH, ANXIETY	3	3	3	3	2	2	
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	1	
				11.SELF-AGGRESSION	1	1	1	1	1	1	
				12.GLOBAL EVALUATION	3	3	3	2	2	2	
11.Total score	28	29	29	17	17	17					
39	39	Imipramine	Female	01.FACIAL EXPRESSION	3	3	2	1	1	1	1
				02.BODY GESTURES	3	3	2	2	2	1	

1405

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10

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/3	39	Imipramine	Female	03. LOOK	2	2	2	1	1	0	0
				04. OUTWARD APPEARANCE	2	2	2	1	0	0	
				05. SPEECH	2	1	2	1	0	0	
				06. VOICE	2	2	1	1	1	0	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	0	
				08. CONTACTS, AFFECTIVE NEED	3	3	2	1	1	0	
				09. ANGUISH, ANXIETY	3	3	1	1	2	1	
				10. AGGRESSION, IRRITABILITY	3	3	2	1	2	1	
				11. SELF-AGGRESSION	2	1	1	1	1	0	
				12. GLOBAL EVALUATION	3	3	2	1	1	0	
				11. Total score	30	27	20	12	12	7	2
				40	Reboxetine	Female	01. FACIAL EXPRESSION	0	1	1	1
02. BODY GESTURES	1	1	1				1	1	1		
03. LOOK	1	0	1				0	0	1		
04. OUTWARD APPEARANCE	2	0	0				1	1	1		
05. SPEECH	3	1	1				0	0	1		
06. VOICE	0	0	0				0	0	0		
07. ADAPTABILITY, SUGGESTIBILITY	2	1	1				1	1	0		
08. CONTACTS, AFFECTIVE NEED	2	0	0				0	0	1		
09. ANGUISH, ANXIETY	1	1	1				1	0	1		
10. AGGRESSION, IRRITABILITY	2	2	1				0	0	1		
11. SELF-AGGRESSION	3	0	0				0	0	0		
12. GLOBAL EVALUATION	1	0	0				0	0	0		
11. Total score	18	8	7	5	4	5					
41	Placebo	Male	01. FACIAL EXPRESSION	2	2	2	2	2	2	1	2
			02. BODY GESTURES	2	3	2	1	1	1	2	
			03. LOOK	0	1	0	0	0	2	2	
			04. OUTWARD APPEARANCE	2	2	2	2	3	2	2	
			05. SPEECH	2	2	1	1	1	2	1	
			06. VOICE	2	2	0	2	1	1	1	
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	3	2	2	1	1	
			08. CONTACTS, AFFECTIVE NEED	2	1	2	2	1	2	1	
			09. ANGUISH, ANXIETY	1	3	2	1	1	1	1	
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0	
			11. SELF-AGGRESSION	1	1	1	1	1	1	1	
			12. GLOBAL EVALUATION	2	1	1	1	2	0	0	
11. Total score	18	20	16	15	16	14	14				
42	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	2	2	1	2	2
			02. BODY GESTURES	1	2	3	3	2	2	2	
			03. LOOK	3	2	2	2	1	1	2	
			04. OUTWARD APPEARANCE	2	1	1	1	2	0	0	
			05. SPEECH	3	2	2	2	3	2	1	
			06. VOICE	2	1	1	1	2	2	2	
			07. ADAPTABILITY, SUGGESTIBILITY	0	2	1	1	2	2	0	
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2	
			09. ANGUISH, ANXIETY	2	3	1	0	1	2	2	

1406

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11

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/3	42	Imipramine	Female	10. AGGRESSION, IRRITABILITY	1	0	2	0	0	0	0
				11. SELF-AGGRESSION	1	1	0	1	1	0	0
				12. GLOBAL EVALUATION	2	2	2	1	2	1	2
				11..Total score	21	20	20	16	19	14	13
2/4	31	Placebo	Male	01. FACIAL EXPRESSION	3	3	2	2	2	2	2
				02. BODY GESTURES	4	4	3	3	3	3	2
				03. LOOK	3	3	3	3	3	2	
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	
				05. SPEECH	3	3	2	2	1	1	
				06. VOICE	1	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	1	1	
				08. CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0	
				09. ANGUISH, ANXIETY	4	3	3	3	3	3	
				10. AGGRESSION, IRRITABILITY	4	3	3	3	3	3	
				11. SELF-AGGRESSION	3	3	2	2	2	2	
				12. GLOBAL EVALUATION	2	2	2	2	2	2	
				11..Total score	30	29	25	25	22	19	
14/07	32	Reboxetine	Male	01. FACIAL EXPRESSION	3	3	2	3	2	1	0
				02. BODY GESTURES	3	3	3	3	1	1	
				03. LOOK	3	3	3	2	1	1	
				04. OUTWARD APPEARANCE	2	2	1	1	1	1	
				05. SPEECH	3	3	3	2	1	0	
				06. VOICE	4	4	4	2	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	1	0	
				08. CONTACTS, AFFECTIVE NEED	3	3	3	3	1	1	
				09. ANGUISH, ANXIETY	4	4	4	3	1	0	
				10. AGGRESSION, IRRITABILITY	4	3	3	2	2	1	
				11. SELF-AGGRESSION	2	2	1	1	1	1	
				12. GLOBAL EVALUATION	3	3	2	2	1	1	
				11..Total score	37	36	33	27	14	8	
33	Imipramine	Male	01. FACIAL EXPRESSION	3	3	2	1	1	1	1	1
			02. BODY GESTURES	3	3	3	2	1	1		
			03. LOOK	2	2	2	2	0	0		
			04. OUTWARD APPEARANCE	0	0	0	0	1	0		
			05. SPEECH	1	1	1	0	1	0		
			06. VOICE	1	1	1	0	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	0	0		
			08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1		
			09. ANGUISH, ANXIETY	2	2	2	2	0	0		
			10. AGGRESSION, IRRITABILITY	1	1	1	0	0	0		
			11. SELF-AGGRESSION	1	1	1	0	0	0		
			12. GLOBAL EVALUATION	2	2	2	1	0	0		
				11..Total score	20	20	18	11	5	4	
34	Placebo	Female	01. FACIAL EXPRESSION	4	4	4	3	2	1	1	
			11..Total score	4	4	4	3	2	1		

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12

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/4	34	Placebo	Female	02. BODY GESTURES	4	4	3	3	2	1	1
				03. LOOK	4	4	4	3	2	1	
				04. OUTWARD APPEARANCE	4	4	4	3	1	1	
				05. SPEECH	4	4	3	3	2	1	
				06. VOICE	4	4	4	3	2	1	
				07. ADAPTABILITY, SUGGESTIBILITY	4	3	3	2	2	1	
				08. CONTACTS, AFFECTIVE NEED	4	3	3	3	2	1	
				09. ANGUISH, ANXIETY	4	4	4	4	2	1	
				10. AGGRESSION, IRRITABILITY	2	2	2	2	2	1	
				11. SELF-AGGRESSION	3	3	3	2	1	1	
				12. GLOBAL EVALUATION	44	43	41	33	20	12	
35	Reboxetine	Female	01. FACIAL EXPRESSION	3	3	3	2	2	1	1	0
			02. BODY GESTURES	3	3	3	2	2	1		
			03. LOOK	4	3	2	2	2	1		
			04. OUTWARD APPEARANCE	3	3	2	2	2	1		
			05. SPEECH	4	4	3	2	1	0		
			06. VOICE	2	2	2	2	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	2	2	1		
			08. CONTACTS, AFFECTIVE NEED	4	4	3	2	2	1		
			09. ANGUISH, ANXIETY	4	4	4	3	2	1		
			10. AGGRESSION, IRRITABILITY	4	4	4	3	2	1		
			11. SELF-AGGRESSION	3	3	3	2	2	1		
12. GLOBAL EVALUATION	3	3	3	2	1	1					
11. Total score	40	39	33	24	19	12					
36	Imipramine	Female	01. FACIAL EXPRESSION	4	3	3	2	2	1	1	0
			02. BODY GESTURES	3	3	3	2	1	1		
			03. LOOK	3	3	3	2	2	1		
			04. OUTWARD APPEARANCE	4	4	3	2	2	1		
			05. SPEECH	3	3	3	2	1	0		
			06. VOICE	4	4	4	2	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	4	4	3	2	1	1		
			08. CONTACTS, AFFECTIVE NEED	4	4	3	2	1	0		
			09. ANGUISH, ANXIETY	4	3	3	2	1	0		
			10. AGGRESSION, IRRITABILITY	2	2	2	2	1	1		
			11. SELF-AGGRESSION	2	2	2	2	1	1		
12. GLOBAL EVALUATION	3	3	2	2	1	0					
11. Total score	40	37	32	24	13	8					
2/5	73	Placebo	Male	01. FACIAL EXPRESSION	1	1	0	1	1	1	2
				02. BODY GESTURES	2	1	1	1	1	1	
				03. LOOK	2	1	1	1	1	1	
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	
				05. SPEECH	3	2	1	2	2	2	
				06. VOICE	2	1	1	1	2	2	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	2	2	
				08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	2	

1408

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13

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PHARMACIA CNS R8D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
2/5	73	Placebo	Male	09. ANGUISH, ANXIETY	2	1	2	1	1	2	2				
				10. AGGRESSION, IRRITABILITY	2	2	1	1	1	2					
				11. SELF-AGGRESSION	2	1	1	1	1	2					
				12. GLOBAL EVALUATION	2	1	1	1	2	2					
				11. Total score	22	14	10	12	15	18	20				
				74	Reboxetine	Male	01. FACIAL EXPRESSION	1	1	1	1	1	1	0	0
							02. BODY GESTURES	1	1	0	0	0	0	0	
							03. LOOK	2	1	0	0	0	1	0	
							04. OUTWARD APPEARANCE	1	1	0	1	1	0	0	
							05. SPEECH	3	2	0	0	1	0	0	
							06. VOICE	2	1	0	0	0	0	0	
							07. ADAPTABILITY, SUGGESTIBILITY	2	0	0	0	0	0	1	
08. CONTACTS, AFFECTIVE NEED	2	1	1				1	0	0	0					
09. ANGUISH, ANXIETY	3	1	1				1	0	1	1					
10. AGGRESSION, IRRITABILITY	2	0	1				0	0	0	0					
11. SELF-AGGRESSION	1	0	1				0	0	0	0					
12. GLOBAL EVALUATION	2	2	1				0	1	0	0					
11. Total score	22	11	6	3	4	2	2								
75	Imipramine	Male	01. FACIAL EXPRESSION	2	2	0	0	0	0	0	0				
			02. BODY GESTURES	2	1	0	0	0	0	0					
			03. LOOK	2	1	1	0	1	0	0					
			04. OUTWARD APPEARANCE	1	2	0	0	1	0	0					
			05. SPEECH	3	2	0	1	0	0	0					
			06. VOICE	1	0	0	0	0	0	0					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	0	0	1	0	0					
			08. CONTACTS, AFFECTIVE NEED	1	1	0	0	0	1	0					
			09. ANGUISH, ANXIETY	3	2	2	0	0	1	1					
			10. AGGRESSION, IRRITABILITY	3	2	2	0	0	0	1					
			11. SELF-AGGRESSION	0	0	0	0	0	0	0					
			12. GLOBAL EVALUATION	3	2	0	0	0	0	0					
11. Total score	23	17	5	1	2	2	2								
76	Imipramine	Female	01. FACIAL EXPRESSION	2	2	0	0	2	0	0	0				
			02. BODY GESTURES	2	1	0	0	3	0	0					
			03. LOOK	2	1	0	2	0	1	0					
			04. OUTWARD APPEARANCE	2	1	0	2	0	1	0					
			05. SPEECH	1	1	0	1	0	0	0					
			06. VOICE	0	0	0	1	0	0	0					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	0	1	0	1	1					
			08. CONTACTS, AFFECTIVE NEED	2	2	1	2	0	0	0					
			09. ANGUISH, ANXIETY	3	2	2	2	0	0	0					
			10. AGGRESSION, IRRITABILITY	1	1	3	1	0	0	0					
			11. SELF-AGGRESSION	0	0	0	0	0	0	0					
			12. GLOBAL EVALUATION	3	3	1	3	0	0	0					
11. Total score	20	16	7	20	1	3	1								

1409

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14

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PHARMACIA CNS 88D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/5	77	Placebo	Male	01. FACIAL EXPRESSION	2	0	1	0	0	0	0
				02. BODY GESTURES	2	1	0	1	0	0	0
				03. LOOK	1	2	0	0	0	0	
				04. OUTWARD APPEARANCE	3	1	1	0	0	0	
				05. SPEECH	2	0	2	1	0	1	
				06. VOICE	1	0	1	1	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	0	0	
				08. CONTACTS, AFFECTIVE NEED	2	0	1	0	1	0	
				09. ANGUISH, ANXIETY	2	2	1	1	0	1	
				10. AGGRESSION, IRRITABILITY	0	1	1	1	0	0	
				11. SELF-AGGRESSION	0	0	0	0	0	0	
				12. GLOBAL EVALUATION	3	1	0	0	0	0	
11..Total score	19	9	9	5	2	1					
78	Reboxetine	Female	01. FACIAL EXPRESSION	1	1	0	1	0	0	0	0
			02. BODY GESTURES	2	1	1	0	0	0		
			03. LOOK	2	1	0	1	1	1		
			04. OUTWARD APPEARANCE	2	1	0	0	1	0		
			05. SPEECH	1	0	0	0	0	0		
			06. VOICE	1	0	0	1	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	0	1	2	0	1	0		
			08. CONTACTS, AFFECTIVE NEED	2	0	2	1	0	1		
			09. ANGUISH, ANXIETY	2	2	2	2	0	0		
			10. AGGRESSION, IRRITABILITY	2	2	1	2	0	0		
			11. SELF-AGGRESSION	0	0	0	0	0	0		
			12. GLOBAL EVALUATION	2	3	2	2	0	0		
11..Total score	17	13	10	10	3	2					
2/6	55	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	1	0	0	0	0
				02. BODY GESTURES	2	2	1	0	0	0	
				03. LOOK	3	2	1	0	0	0	
				04. OUTWARD APPEARANCE	2	2	1	0	0	0	
				05. SPEECH	2	2	1	0	0	0	
				06. VOICE	2	2	1	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	0	0	0	
				08. CONTACTS, AFFECTIVE NEED	2	2	1	0	0	0	
				09. ANGUISH, ANXIETY	3	2	1	1	1	1	
				10. AGGRESSION, IRRITABILITY	2	2	1	1	0	0	
				11. SELF-AGGRESSION	2	1	0	0	0	0	
				12. GLOBAL EVALUATION	2	2	1	0	0	0	
11..Total score	26	23	11	2	1	1					
56	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	2	1	1	1	2
			02. BODY GESTURES	2	2	2	2	1	1	2	
			03. LOOK	2	2	2	2	1	1	2	
			04. OUTWARD APPEARANCE	2	2	2	2	1	1	2	
			05. SPEECH	2	1	1	1	1	1	2	
			06. VOICE	2	1	1	1	1	1	2	
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	1	1	2	

1410

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15

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PHARMACIA CNS 3&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
2/6	56	Reboxetine	Female	08. CONTACTS, AFFECTIVE NEED	2	2	2	2	1	1	2				
				09. ANGUISH, ANXIETY	2	2	2	2	1	1	2				
				10. AGGRESSION, IRRITABILITY	2	2	2	2	1	1	2				
				11. SELF-AGGRESSION	1	1	1	1	1	1	2				
				12. GLOBAL EVALUATION	3	3	3	2	1	1	2				
				11..Total score	24	22	22	21	12	12	24				
				57	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	0	0	0	0	0
							02. BODY GESTURES	2	2	1	0	0	0	0	
							03. LOOK	2	2	1	0	0	0	0	
							04. OUTWARD APPEARANCE	2	2	1	0	0	0	0	
							05. SPEECH	2	2	1	0	0	0	0	
							06. VOICE	2	2	0	0	0	0	0	
07. ADAPTABILITY, SUGGESTIBILITY	2	2	1				0	0	0	0					
08. CONTACTS, AFFECTIVE NEED	2	2	1				1	1	0	0					
09. ANGUISH, ANXIETY	2	2	1				0	0	0	0					
10. AGGRESSION, IRRITABILITY	0	1	1				0	0	0	0					
11. SELF-AGGRESSION	0	0	0				0	0	0	0					
12. GLOBAL EVALUATION	1	2	1				0	0	0	0					
11..Total score	22	19	9	1	1	0	0								
58	Placebo	Female	01. FACIAL EXPRESSION	2	2	2	0	0	0	0	0				
			02. BODY GESTURES	3	2	2	0	0	0	0					
			03. LOOK	2	1	1	0	0	0	0					
			04. OUTWARD APPEARANCE	1	1	1	0	0	0	0					
			05. SPEECH	3	2	2	0	0	0	0					
			06. VOICE	1	1	1	0	0	0	0					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	0	0	0	0					
			08. CONTACTS, AFFECTIVE NEED	2	2	1	0	0	0	0					
			09. ANGUISH, ANXIETY	2	2	1	0	0	0	0					
			10. AGGRESSION, IRRITABILITY	1	1	1	0	0	0	0					
			11. SELF-AGGRESSION	1	1	1	0	0	0	0					
			12. GLOBAL EVALUATION	3	2	1	0	0	0	0					
11..Total score	23	18	15	0	0	0	0								
59	Placebo	Male	01. FACIAL EXPRESSION	3	3	2	2	2	2	2	2				
			02. BODY GESTURES	3	3	2	2	2	2	2					
			03. LOOK	2	2	2	2	2	2	2					
			04. OUTWARD APPEARANCE	3	2	2	2	2	2	2					
			05. SPEECH	3	2	2	2	2	2	2					
			06. VOICE	1	2	2	2	2	2	2					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2					
			08. CONTACTS, AFFECTIVE NEED	3	3	2	2	2	2	2					
			09. ANGUISH, ANXIETY	2	2	2	2	2	2	2					
			10. AGGRESSION, IRRITABILITY	2	2	2	2	2	2	2					
			11. SELF-AGGRESSION	2	2	1	1	1	1	1					
			12. GLOBAL EVALUATION	3	3	2	2	2	2	2					
11..Total score	29	28	23	23	23	23	23								

1411

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16

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0
RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
2/6	60	Imipramine	Female	01.FACIAL EXPRESSION	2	2	1	0	0	0	0	0
				02.BODY GESTURES	2	2	1	0	0	0	0	0
				03.LOOK	3	2	1	0	0	0	0	0
				04.OUTWARD APPEARANCE	3	2	1	0	0	0	0	0
				05.SPEECH	2	2	1	0	0	0	0	0
				06.VOICE	2	2	0	0	0	0	0	0
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	1	0	0	0	0	0
				08.CONTACTS, AFFECTIVE NEED	2	2	1	0	0	0	0	0
				09.ANGUISH, ANXIETY	2	2	0	0	0	0	0	0
				10.AGRESSION, IRRITABILITY	2	1	0	0	0	0	0	0
				11.SELF-AGGRESSION	2	1	0	0	0	0	0	0
12.GLOBAL EVALUATION	3	3	1	0	0	0	0	0				
11.Total score	27	23	8	0	0	0	0	0				
3/1	61	Imipramine	Male	01.FACIAL EXPRESSION	2	2	1	1	0	0	0	
				02.BODY GESTURES	2	2	1	1	0	0	0	
				03.LOOK	2	2	1	1	1	1		
				04.OUTWARD APPEARANCE	1	1	1	1	0	0		
				05.SPEECH	1	2	1	1	1	1		
				06.VOICE	1	1	1	1	1	1		
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	0	0		
				08.CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1		
				09.ANGUISH, ANXIETY	2	2	2	1	1	1		
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0		
				11.SELF-AGGRESSION	1	1	1	1	0	0		
12.GLOBAL EVALUATION	1	1	1	1	1	1						
11.Total score	16	17	13	10	5	5						
62	62	Imipramine	Female	01.FACIAL EXPRESSION	2	1	1	1	0	0	0	
				02.BODY GESTURES	2	1	0	0	1	0	0	
				03.LOOK	2	1	1	1	0	0		
				04.OUTWARD APPEARANCE	2	1	0	1	1	1		
				05.SPEECH	2	1	0	1	1	1		
				06.VOICE	2	1	0	0	0	0		
				07.ADAPTABILITY, SUGGESTIBILITY	2	1	0	0	0	0		
				08.CONTACTS, AFFECTIVE NEED	2	1	0	1	1	0		
				09.ANGUISH, ANXIETY	2	1	0	1	1	1		
				10.AGRESSION, IRRITABILITY	2	1	0	1	1	0		
				11.SELF-AGGRESSION	2	1	0	0	0	0		
12.GLOBAL EVALUATION	2	1	0	0	0	1						
11.Total score	24	12	4	7	6	5						
63	63	Placebo	Male	01.FACIAL EXPRESSION	2	2	1	1	1	1	1	
				02.BODY GESTURES	2	2	1	1	1	0		
				03.LOOK	1	1	1	1	1	1		
				04.OUTWARD APPEARANCE	2	2	1	1	0	1		
				05.SPEECH	1	1	1	1	1	1		

1412

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17

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/1	63	Placebo	Male	06.VOICE	1	1	1	1	0	0	0				
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	1	1					
				08.CONTACTS, AFFECTIVE NEED	2	2	2	2	1	1					
				09.ANGUISH, ANXIETY	2	2	2	2	2	2					
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	2					
				11.SELF-AGGRESSION	1	1	1	1	0	1					
				12.GLOBAL EVALUATION	2	2	2	1	1	1					
				11.Total score	19	19	16	16	9	12					
				64	64	Placebo	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2
								02.BODY GESTURES	1	1	1	1	1	1	
								03.LOOK	1	1	1	1	1	1	
								04.OUTWARD APPEARANCE	2	2	2	2	2	2	
05.SPEECH	2	2	2					2	2	2					
06.VOICE	2	2	2					2	2	2					
07.ADAPTABILITY, SUGGESTIBILITY	1	1	1					1	1	1					
08.CONTACTS, AFFECTIVE NEED	1	1	1					1	1	1					
09.ANGUISH, ANXIETY	1	1	1					1	1	1					
10.AGRESSION, IRRITABILITY	0	0	0					0	0	0					
11.SELF-AGGRESSION	1	1	1					1	1	1					
12.GLOBAL EVALUATION	2	2	2					2	2	2					
11.Total score	16	16	16	16	16	16									
65	65	Reboxetine	Male	01.FACIAL EXPRESSION	2	2	1	1	1	1	1				
				02.BODY GESTURES	2	1	1	0	1	1					
				03.LOOK	2	1	1	1	1	0					
				04.OUTWARD APPEARANCE	2	1	1	1	0	0					
				05.SPEECH	2	1	1	1	1	0					
				06.VOICE	2	1	1	1	1	0					
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1					
				08.CONTACTS, AFFECTIVE NEED	2	1	1	1	0	1					
				09.ANGUISH, ANXIETY	2	3	1	1	1	1					
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	1					
				11.SELF-AGGRESSION	3	1	1	1	0	1					
				12.GLOBAL EVALUATION	2	2	1	1	1	1					
11.Total score	23	16	12	11	9	8									
66	66	Reboxetine	Male	01.FACIAL EXPRESSION	2	2	1	1	1	1	1				
				02.BODY GESTURES	3	2	2	2	1	1					
				03.LOOK	1	1	1	1	1	1					
				04.OUTWARD APPEARANCE	2	2	1	1	1	1					
				05.SPEECH	2	2	1	1	1	1					
				06.VOICE	2	2	1	1	1	1					
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1					
				08.CONTACTS, AFFECTIVE NEED	2	2	2	2	1	1					
				09.ANGUISH, ANXIETY	1	1	1	1	0	0					
				10.AGRESSION, IRRITABILITY	1	1	1	1	0	0					
				11.SELF-AGGRESSION	2	2	1	1	1	1					
				12.GLOBAL EVALUATION	2	2	1	1	1	1					

1413

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18

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	66	Reboxetine	Male	11..Total score	23	22	14	14	10	10	10
	139	Imipramine	Male	01..FACIAL EXPRESSION	2	2	3				
				02..BODY GESTURES	2	2	3				
				03..LOOK	1	1	2				
				04..OUTWARD APPEARANCE	2	2	3				
				05..SPEECH	3	3	3				
				06..VOICE	1	1	2				
				07..ADAPTABILITY, SUGGESTIBILITY	2	2	3				
				08..CONTACTS, AFFECTIVE NEED	1	1	3				
				09..ANGUISH, ANXIETY	1	1	3				
				10..AGGRESSION, IRRITABILITY	1	1	3				
				11..SELF-AGGRESSION	1	1	2				
				12..GLOBAL EVALUATION	1	1	2				
				11..Total score	19	19	32				
	140	Placebo	Male	01..FACIAL EXPRESSION	2	2	1	1	1	1	1
				02..BODY GESTURES	2	2	2	0	0	0	0
				03..LOOK	1	1	1	0	0	0	0
				04..OUTWARD APPEARANCE	1	1	1	0	0	0	0
				05..SPEECH	1	1	1	1	1	1	1
				06..VOICE	1	1	1	0	0	0	0
				07..ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	0	0	0
				08..CONTACTS, AFFECTIVE NEED	1	1	1	0	0	0	0
				09..ANGUISH, ANXIETY	1	1	1	1	1	1	1
				10..AGGRESSION, IRRITABILITY	1	1	1	0	0	0	0
				11..SELF-AGGRESSION	1	1	1	0	0	0	0
				12..GLOBAL EVALUATION	1	1	1	0	0	0	0
				11..Total score	14	14	13	3	3	2	2
	141	Placebo	Female	01..FACIAL EXPRESSION	2	2	1	1	1	1	1
				02..BODY GESTURES	2	2	1	1	1	1	1
				03..LOOK	1	1	1	0	0	0	0
				04..OUTWARD APPEARANCE	1	1	1	0	0	0	0
				05..SPEECH	2	2	1	1	1	1	1
				06..VOICE	1	1	1	1	1	1	1
				07..ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08..CONTACTS, AFFECTIVE NEED	1	1	1	0	0	0	0
				09..ANGUISH, ANXIETY	1	1	2	2	2	2	1
				10..AGGRESSION, IRRITABILITY	2	2	2	1	1	1	1
				11..SELF-AGGRESSION	1	1	1	1	1	1	1
				12..GLOBAL EVALUATION	1	1	1	1	1	1	1
				11..Total score	17	17	13	10	9	8	7
	142	Imipramine	Female	01..FACIAL EXPRESSION	1	1	1	1	1	1	1
				02..BODY GESTURES	1	1	1	1	1	1	1
				03..LOOK	1	1	1	1	1	1	1
				04..OUTWARD APPEARANCE	1	1	1	1	1	1	1

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19

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/1	142	Imipramine	Female	05. SPEECH	2	2	2	2							
				06. VOICE	2	2	2	2							
				07. ADAPTABILITY, SUGGESTIBILITY	2	3	3	3							
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2							
				09. ANGUISH, ANXIETY	2	2	2	2							
				10. AGGRESSION, IRRITABILITY	2	2	2	2							
				11. SELF-AGGRESSION	1	1	1	1							
				12. GLOBAL EVALUATION	2	2	2	2							
				11. Total score	19	20	20	21							
				143	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	1	0	0	0	0
							02. BODY GESTURES	1	1	1	1	0	0		
03. LOOK	1	1	1				1	0	0						
04. OUTWARD APPEARANCE	1	1	1				1	0	0						
05. SPEECH	1	1	1				1	0	0						
06. VOICE	2	0	0				0	0	0						
07. ADAPTABILITY, SUGGESTIBILITY	1	1	1				1	1	1						
08. CONTACTS, AFFECTIVE NEED	1	1	1				1	1	1						
09. ANGUISH, ANXIETY	2	1	1				1	1	1						
10. AGGRESSION, IRRITABILITY	2	2	2				2	1	0						
11. SELF-AGGRESSION	1	0	0				0	0	0						
12. GLOBAL EVALUATION	2	1	1	1	1	1									
11. Total score	17	11	11	7	7	6									
144	Reboxetine	Female	01. FACIAL EXPRESSION	1	1	1	1	0	0	0	0				
			02. BODY GESTURES	1	1	1	1	0	0						
			03. LOOK	1	1	1	1	0	0						
			04. OUTWARD APPEARANCE	0	0	0	0	0	0						
			05. SPEECH	1	1	1	1	1	1						
			06. VOICE	2	2	2	2	1	1						
			07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0						
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1						
			09. ANGUISH, ANXIETY	1	1	1	1	1	1						
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0						
			11. SELF-AGGRESSION	0	0	0	0	0	0						
12. GLOBAL EVALUATION	1	1	1	1	1	1									
11. Total score	9	9	8	5	4	4									
451	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	2	3							
			02. BODY GESTURES	2	2	2	2	1	1						
			03. LOOK	1	1	1	1	2	2						
			04. OUTWARD APPEARANCE	1	1	1	1	2	2						
			05. SPEECH	2	2	2	2	2	2						
			06. VOICE	1	1	1	1	2	2						
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2						
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	2	2						
			09. ANGUISH, ANXIETY	2	2	2	2	2	2						
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0						
			11. SELF-AGGRESSION	1	1	1	1	1	1						

1415

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20

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
3/1	451	Reboxetine	Female	12.GLOBAL EVALUATION	1	1	2					
			11.Total score	16	16	23						
	452	Placebo	Male	01.FACIAL EXPRESSION	2	1	0	0	0	0	1	1
				02.BODY GESTURES	2	1	0	0	0	1	1	
				03.LOOK	1	1	1	0	0	0	0	
				04.OUTWARD APPEARANCE	1	1	1	0	0	0	0	
				05.SPEECH	1	1	1	0	0	1	1	
				06.VOICE	1	1	1	0	0	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	0	1	1	
				08.CONTACTS, AFFECTIVE NEED	1	1	1	0	0	1	1	
				09.ANGUISH, ANXIETY	2	2	1	0	0	2	0	
				10.AGRESSION, IRRITABILITY	1	1	0	1	1	1	0	
11.SELF-AGGRESSION	1	1	1	0	0	1	0					
12.GLOBAL EVALUATION	1	1	1	0	0	1	1					
11.Total score	15	13	8	1	1	11	7					
453	Imipramine	Female	01.FACIAL EXPRESSION	2	1	1	0	0	0	0	0	
			02.BODY GESTURES	2	1	1	0	0	0	0		
			03.LOOK	2	1	1	0	0	0	0		
			04.OUTWARD APPEARANCE	1	1	1	0	0	0	0		
			05.SPEECH	1	1	1	0	0	0	0		
			06.VOICE	2	1	1	0	1	0	0		
			07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1		
			08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1		
			09.ANGUISH, ANXIETY	2	1	1	1	0	1	1		
			10.AGRESSION, IRRITABILITY	0	1	1	1	1	0	0		
			11.SELF-AGGRESSION	1	1	1	0	0	0	0		
			12.GLOBAL EVALUATION	2	1	1	0	1	1	1		
11.Total score	17	12	12	4	4	5						
454	Reboxetine	Male	01.FACIAL EXPRESSION	2	1	1	0	0	0	0	0	
			02.BODY GESTURES	1	0	0	0	0	0	0		
			03.LOOK	1	1	1	0	0	0	0		
			04.OUTWARD APPEARANCE	2	1	1	0	0	0	0		
			05.SPEECH	1	0	0	0	0	0	0		
			06.VOICE	1	0	0	0	0	0	0		
			07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	0	0	0		
			08.CONTACTS, AFFECTIVE NEED	2	1	1	1	1	1	1		
			09.ANGUISH, ANXIETY	1	0	0	0	0	0	0		
			10.AGRESSION, IRRITABILITY	1	0	0	0	0	0	0		
			11.SELF-AGGRESSION	0	0	0	0	0	0	0		
			12.GLOBAL EVALUATION	1	1	1	0	1	1	1		
11.Total score	15	7	7	3	1	2						
455	Placebo	Female	01.FACIAL EXPRESSION	2	2	1	1	1	1	1	1	
			02.BODY GESTURES	1	1	1	0	1	1	1		
			03.LOOK	2	2	1	0	1	1	1		

1416

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21

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PHARMACIA CNS RED
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/1	455	Placebo	Female	04. OUTWARD APPEARANCE	2	2	1	1	2	2	1				
				05. SPEECH	1	1	1	1	1	0	0				
				06. VOICE	2	1	1	1	0	0					
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1					
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1					
				09. ANGUISH, ANXIETY	2	2	2	2	2	2					
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0					
				11. SELF-AGGRESSION	0	0	0	0	0	0					
				12. GLOBAL EVALUATION	2	2	1	1	1	1					
				11.Total score	16	15	11	9	10	9					
				456	Imipramine	Female	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	1
							02. BODY GESTURES	1	1	1	1	1	1		
03. LOOK	1	1	1				1	1	1						
04. OUTWARD APPEARANCE	1	1	1				1	1	1						
05. SPEECH	1	1	1				1	1	1						
06. VOICE	1	1	1				1	1	1						
07. ADAPTABILITY, SUGGESTIBILITY	1	1	1				1	1	1						
08. CONTACTS, AFFECTIVE NEED	1	1	1				1	1	1						
09. ANGUISH, ANXIETY	1	1	1				1	1	1						
10. AGGRESSION, IRRITABILITY	1	1	1				1	1	1						
11. SELF-AGGRESSION	1	1	1				1	1	1						
12. GLOBAL EVALUATION	1	1	1				1	1	1						
11.Total score	12	12	12	12	12	12									
3/2	65/A	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	1	2	2	1	2				
				02. BODY GESTURES	2	1	1	1	2	1					
				03. LOOK	1	1	0	1	2	1					
				04. OUTWARD APPEARANCE	0	0	0	0	0	0					
				05. SPEECH	2	1	1	1	1	1					
				06. VOICE	1	1	0	1	1	1					
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	2	1	1					
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2					
				09. ANGUISH, ANXIETY	1	1	1	0	1	1					
				10. AGGRESSION, IRRITABILITY	3	1	1	1	1	1					
				11. SELF-AGGRESSION	2	1	1	1	2	1					
				12. GLOBAL EVALUATION	2	2	1	1	2	2					
11.Total score	20	15	11	13	17	14									
3/3	67	Placebo	Male	01. FACIAL EXPRESSION	5	2	3	2	1	0	1				
				02. BODY GESTURES	5	1	2	1	1	1					
				03. LOOK	2	2	2	1	1	1					
				04. OUTWARD APPEARANCE	1	1	1	0	0	0					
				05. SPEECH	1	1	2	1	0	0					
				06. VOICE	0	0	2	0	0	0					
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	3	1	1	1					
				08. CONTACTS, AFFECTIVE NEED	2	2	3	2	2	1					
				09. ANGUISH, ANXIETY	2	0	3	0	2	0					
				10. AGGRESSION, IRRITABILITY	0	2	0	0	0	0					

1417

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22

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/3	67	Placebo	Male	11. SELF-AGGRESSION	1	1	1	1	1	1	1
				12. GLOBAL EVALUATION	2	2	2	1	1	1	
				11.Total score	19	15	24	10	10	6	10
68	Reboxetine	Male	01. FACIAL EXPRESSION	2	1	1	1	1	0	0	0
			02. BODY GESTURES	3	1	1	0	0	0	0	
			03. LOOK	1	1	1	0	0	0		
			04. OUTWARD APPEARANCE	1	1	0	0	0	0		
			05. SPEECH	3	2	1	0	0	0		
			06. VOICE	2	1	0	0	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	0	0		
			08. CONTACTS, AFFECTIVE NEED	2	2	1	1	0	0		
			09. ANGUISH, ANXIETY	2	1	0	0	0	0		
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0		
			11. SELF-AGGRESSION	1	0	1	0	0	0		
12. GLOBAL EVALUATION	2	1	1	0	0	0					
11.Total score	21	13	8	3	0	0	0				
69	Placebo	Male	01. FACIAL EXPRESSION	2	2	1	1	1	3	1	1
			02. BODY GESTURES	3	3	1	1	2	1	1	
			03. LOOK	1	2	1	0	2	0	0	
			04. OUTWARD APPEARANCE	1	1	1	0	2	1	0	
			05. SPEECH	2	2	2	1	3	1	1	
			06. VOICE	1	1	1	1	1	1	2	
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	2	1	1	
			08. CONTACTS, AFFECTIVE NEED	3	3	1	0	3	2	2	
			09. ANGUISH, ANXIETY	3	3	2	1	3	1	1	
			10. AGGRESSION, IRRITABILITY	2	4	1	1	3	1	1	
			11. SELF-AGGRESSION	2	2	2	1	2	1	1	
12. GLOBAL EVALUATION	2	3	1	1	3	1	1				
11.Total score	24	28	15	9	29	12	12				
70	Imipramine	Male	01. FACIAL EXPRESSION	3	2	1	1	1	1	0	0
			02. BODY GESTURES	2	2	1	1	1	1	1	
			03. LOOK	1	1	0	0	0	0	0	
			04. OUTWARD APPEARANCE	2	1	1	0	0	0	0	
			05. SPEECH	2	1	1	0	0	0	1	
			06. VOICE	1	1	1	2	0	0	1	
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	2	1	1	0	0	
			08. CONTACTS, AFFECTIVE NEED	2	1	0	1	1	0	0	
			09. ANGUISH, ANXIETY	3	2	1	1	1	0	0	
			10. AGGRESSION, IRRITABILITY	1	1	0	0	1	0	0	
			11. SELF-AGGRESSION	2	2	1	0	0	0	0	
12. GLOBAL EVALUATION	2	2	1	1	0	0	0				
11.Total score	23	17	10	8	7	3	5				
71	Imipramine	Female	01. FACIAL EXPRESSION	1	1	0	0	0	0	0	
			02. BODY GESTURES	1	1	0	0	0	0	0	

9550082

23

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PHARMACIA CNS 88D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
3/3	71	Imipramine	Female	03. LOOK	0	1	0	0	0	0	0	0
				04. OUTWARD APPEARANCE	1	0	0	0	0	0	0	0
				05. SPEECH	1	1	1	1	1	1	1	
				06. VOICE	0	0	0	0	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	2	0	1	1	0	0	0	
				09. ANGUISH, ANXIETY	2	2	2	1	1	1	1	
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0	
				11. SELF-AGGRESSION	1	2	1	1	1	1	1	
				12. GLOBAL EVALUATION	1	1	1	1	1	1	1	
				11..Total score	11	10	7	5	1	0	0	
72	Reboxetine	Male	01. FACIAL EXPRESSION	2	2	1	1	0	1	1	1	
			02. BODY GESTURES	2	2	1	1	0	1	1		
			03. LOOK	1	1	1	1	1	1	1		
			04. OUTWARD APPEARANCE	1	1	1	1	0	0	0		
			05. SPEECH	2	1	1	1	1	1	1		
			06. VOICE	1	1	1	1	0	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	2		
			08. CONTACTS, AFFECTIVE NEED	2	1	1	1	1	1	2		
			09. ANGUISH, ANXIETY	1	1	2	1	1	1	2		
			10. AGGRESSION, IRRITABILITY	0	3	1	1	1	1	2		
			11. SELF-AGGRESSION	1	1	1	1	1	1	2		
12. GLOBAL EVALUATION	2	1	1	1	1	1	2					
11..Total score	17	16	13	7	10	10	15					
3/4	79	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	0	0	0	
				02. BODY GESTURES	1	1	1	1	1	1	0	
				03. LOOK	1	0	0	0	0	0	0	
				04. OUTWARD APPEARANCE	1	1	1	1	0	0	0	
				05. SPEECH	1	1	1	1	1	1	1	
				06. VOICE	2	1	1	1	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	0	0	0	
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	1	
				09. ANGUISH, ANXIETY	2	1	1	1	0	0	0	
				10. AGGRESSION, IRRITABILITY	1	1	1	1	0	0	0	
				11. SELF-AGGRESSION	1	1	1	1	1	1	1	
12. GLOBAL EVALUATION	2	1	1	1	1	1	1					
11..Total score	17	13	12	7	4	3						
80	Imipramine	Male	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1	
			02. BODY GESTURES	1	1	1	1	1	1	1		
			03. LOOK	1	1	0	0	0	0	0		
			04. OUTWARD APPEARANCE	0	0	0	0	0	0	0		
			05. SPEECH	1	1	1	1	1	1	1		
			06. VOICE	2	1	1	1	1	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1		
			08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	1		
			09. ANGUISH, ANXIETY	1	1	1	1	1	1	1		

1419

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24

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012/4/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
3/4	80	Inipramine	Male	10. AGGRESSION, IRRITABILITY	2	1	1	0	0	0	0	
				11. SELF-AGGRESSION	1	1	1	1	1	1		
				12. GLOBAL EVALUATION	2	2	1	1	1	1		
				11. Total score	16	14	11	8	8	8	8	
81	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	0	0	0	0	0	0	0
			02. BODY GESTURES	2	1	0	0	0	0	0	0	0
			03. LOOK	1	0	0	0	0	0	0	0	0
			04. OUTWARD APPEARANCE	1	0	0	0	0	0	0	0	0
			05. SPEECH	3	1	0	0	0	0	0	0	0
			06. VOICE	2	1	0	0	0	0	0	0	0
			07. ADAPTABILITY, SUGGESTIBILITY	1	0	0	0	0	0	0	0	0
			08. CONTACTS, AFFECTIVE NEED	2	1	0	0	0	0	0	0	0
			09. ANGUISH, ANXIETY	3	1	1	1	1	1	1	1	1
			10. AGGRESSION, IRRITABILITY	0	1	0	0	0	0	0	0	0
			11. SELF-AGGRESSION	1	1	1	1	1	1	1	1	1
			12. GLOBAL EVALUATION	1	1	1	0	0	0	0	0	0
				11. Total score	19	9	2	1	2	2	1	
82	Placebo	Male	01. FACIAL EXPRESSION	2	2	1	1	0	0	0	0	1
			02. BODY GESTURES	1	1	1	1	0	0	0	0	0
			03. LOOK	1	1	1	1	1	1	0	0	0
			04. OUTWARD APPEARANCE	0	0	0	0	0	0	0	0	0
			05. SPEECH	2	2	1	1	1	1	1	1	1
			06. VOICE	2	1	1	1	1	1	1	1	1
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	0	0	0	0	0
			08. CONTACTS, AFFECTIVE NEED	2	1	1	0	0	0	0	0	0
			09. ANGUISH, ANXIETY	2	1	1	0	0	0	0	0	0
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1	1
			11. SELF-AGGRESSION	1	1	1	0	0	0	0	0	0
			12. GLOBAL EVALUATION	1	1	1	1	1	1	1	1	1
				11. Total score	15	13	8	4	3	2	3	
83	Placebo	Male	01. FACIAL EXPRESSION	2	2	2	2	2	2	2	2	
			02. BODY GESTURES	2	2	2	2	2	2	2		
			03. LOOK	1	1	1	1	1	1			
			04. OUTWARD APPEARANCE	0	0	0	0	0	0			
			05. SPEECH	0	0	0	0	0	0			
			06. VOICE	2	2	2	2	2	2			
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2			
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2			
			09. ANGUISH, ANXIETY	2	2	2	2	2	2			
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1			
			11. SELF-AGGRESSION	1	1	1	1	1	1			
			12. GLOBAL EVALUATION	2	2	2	2	2	2			
				11. Total score	18	21	21	21	21	21		
84	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	1	1	0	0	0	
			11. Total score	2	1	1	1	1	0	0	0	

1420

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25

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/4	84	Reboxetine	Female	02. BODY GESTURES	1	0	0	0	0	0	0
				03. LOOK	1	1	1	0	0	0	
				04. OUTWARD APPEARANCE	1	0	0	0	0		
				05. SPEECH	1	1	1	0	0		
				06. VOICE	2	1	0	0	0		
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	0		
				08. CONTACTS, AFFECTIVE NEED	2	2	1	0	0		
				09. ANGUISH, ANXIETY	2	2	1	1	1		
				10. AGGRESSION, IRRITABILITY	1	0	0	0	0		
				11. SELF-AGGRESSION	1	1	1	0	0		
				12. GLOBAL EVALUATION	2	2	1	1	1		
				11.Total score	17	12	8	3	2	2	
				85	Imipramine	Female	01. FACIAL EXPRESSION	1	1	1	1
02. BODY GESTURES	1	0	0				0	0	0		
03. LOOK	1	0	0				0	0	0		
04. OUTWARD APPEARANCE	0	0	0				0	0	0		
05. SPEECH	2	1	0				0	0	0		
06. VOICE	0	0	0				0	0	0		
07. ADAPTABILITY, SUGGESTIBILITY	0	1	1				0	0	0		
08. CONTACTS, AFFECTIVE NEED	1	1	0				0	0	0		
09. ANGUISH, ANXIETY	2	1	1				1	2	1		
10. AGGRESSION, IRRITABILITY	1	0	0				0	0	0		
11. SELF-AGGRESSION	1	0	0				0	0	0		
12. GLOBAL EVALUATION	1	1	1				0	0	0		
11.Total score	12	6	4				2	6	3		
86	Imipramine	Male	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1
			02. BODY GESTURES	1	1	1	1	1	1		
			03. LOOK	1	1	0	0	0	0		
			04. OUTWARD APPEARANCE	1	1	0	0	0	0		
			05. SPEECH	2	1	1	1	1	1		
			06. VOICE	3	2	1	0	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1		
			08. CONTACTS, AFFECTIVE NEED	2	2	1	0	0	0		
			09. ANGUISH, ANXIETY	3	2	1	1	1	2		
			10. AGGRESSION, IRRITABILITY	2	1	1	0	0	0		
			11. SELF-AGGRESSION	1	1	1	1	1	1		
			12. GLOBAL EVALUATION	2	2	1	1	1	1		
			11.Total score	22	17	10	7	7	8		
87	Placebo	Female	01. FACIAL EXPRESSION	2	2	1	0	0	1	1	1
			02. BODY GESTURES	1	1	1	0	1	1		
			03. LOOK	1	1	1	0	1	0		
			04. OUTWARD APPEARANCE	0	0	0	0	0	0		
			05. SPEECH	2	2	1	1	2	1		
			06. VOICE	1	1	1	1	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	2	1		
			08. CONTACTS, AFFECTIVE NEED	2	2	1	1	2	2		

1421

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26

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/4	87	Placebo	Female	09. ANGUISH, ANXIETY	1	1	1	1	2	2	2				
				10. AGGRESSION, IRRITABILITY	0	0	0	1	2	1	1				
				11. SELF-AGGRESSION	2	1	1	1	3	1	1				
				12. GLOBAL EVALUATION	2	2	1	1	1	1	1				
				11. Total score	15	14	10	7	17	12	12				
				88	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	1
							02. BODY GESTURES	1	1	1	0	0	0	0	
							03. LOOK	1	0	0	0	0	0	0	
							04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	
							05. SPEECH	2	1	1	1	1	0	0	
							06. VOICE	1	1	0	0	0	0	0	
							07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	
08. CONTACTS, AFFECTIVE NEED	2	2	1				1	1	1	1					
09. ANGUISH, ANXIETY	2	1	1				1	1	1	1					
10. AGGRESSION, IRRITABILITY	2	1	1				1	1	1	1					
11. SELF-AGGRESSION	2	1	1				1	1	0	0					
12. GLOBAL EVALUATION	2	2	1				1	1	1	1					
11. Total score	17	13	10	9	7	7	7								
89	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	2	2	2	1	0				
			02. BODY GESTURES	2	2	1	1	1	1	1					
			03. LOOK	2	1	1	0	0	0	0					
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1					
			05. SPEECH	1	1	1	1	1	1	1					
			06. VOICE	2	1	1	1	1	1	0					
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1					
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	1	1					
			09. ANGUISH, ANXIETY	2	2	2	2	2	1	1					
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1					
			11. SELF-AGGRESSION	3	0	0	0	0	0	0					
			12. GLOBAL EVALUATION	20	16	15	13	13	9	7					
90	Reboxetine	Male	01. FACIAL EXPRESSION	1	1	1	1	1	0	0	0				
			02. BODY GESTURES	1	1	1	1	1	0	0					
			03. LOOK	0	0	0	0	0	0	0					
			04. OUTWARD APPEARANCE	0	0	0	0	0	0	0					
			05. SPEECH	1	1	1	0	0	0	0					
			06. VOICE	0	0	0	0	0	0	0					
			07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0					
			08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	0					
			09. ANGUISH, ANXIETY	1	1	2	1	1	1	0					
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	0	0					
			11. SELF-AGGRESSION	1	1	0	0	0	0	0					
			12. GLOBAL EVALUATION	9	9	8	6	4	2	0					

1422

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27

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
3/4	457	Placebo	Female	01.FACIAL EXPRESSION	1	1	1	2				
				02.BODY GESTURES	1	1	1	1				
				03.LOOK	1	1	1	1				
				04.OUTWARD APPEARANCE	1	1	1	1				
				05.SPEECH	2	2	2	2				
				06.VOICE	1	1	1	1				
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1				
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1				
				09.ANGUISH, ANXIETY	1	1	1	2				
				10.AGRESSION, IRRITABILITY	1	1	1	1				
				11.SELF-AGGRESSION	1	1	1	1				
				12.GLOBAL EVALUATION	0	0	0	0				
11.Total score	12	12	12	14								
458	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	3						
			02.BODY GESTURES	1	1	2						
			03.LOOK	1	1	1						
			04.OUTWARD APPEARANCE	1	2	2						
			05.SPEECH	2	2	2						
			06.VOICE	1	1	2						
			07.ADAPTABILITY, SUGGESTIBILITY	2	2	2						
			08.CONTACTS, AFFECTIVE NEED	2	2	2						
			09.ANGUISH, ANXIETY	1	1	2						
			10.AGRESSION, IRRITABILITY	1	1	1						
			11.SELF-AGGRESSION	1	1	3						
			12.GLOBAL EVALUATION	1	1	2						
11.Total score	16	18	24									
459	Placebo	Female	01.FACIAL EXPRESSION	2	1	1	1	1	1	1	0	
			02.BODY GESTURES	2	1	1	1	1	1	0	0	0
			03.LOOK	1	1	1	0	0	0	0	0	0
			04.OUTWARD APPEARANCE	1	1	1	0	0	0	0	0	0
			05.SPEECH	2	2	2	1	1	1	0	0	0
			06.VOICE	1	1	1	1	1	1	0	0	0
			07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	0	0	0
			08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	0	0	0
			09.ANGUISH, ANXIETY	2	2	2	2	1	1	1	1	1
			10.AGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1	1
			11.SELF-AGGRESSION	2	1	1	1	1	1	1	1	1
			12.GLOBAL EVALUATION	2	1	1	1	1	1	0	0	0
11.Total score	19	14	15	10	5	7	3					
460	Reboxetine	Male	01.FACIAL EXPRESSION	0	0							
			02.BODY GESTURES	1	1							
			03.LOOK	0	0							
			04.OUTWARD APPEARANCE	0	0							
			05.SPEECH	2	2							
			06.VOICE	0	0							
			07.ADAPTABILITY, SUGGESTIBILITY	0	2							

1423

9550082

28

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
3/4	460	Reboxetine	Male	08. CONTACTS, AFFECTIVE NEED	2	2									
				09. ANGUISH, ANXIETY	2	2									
				10. AGGRESSION, IRRITABILITY	1	1									
				11. SELF-AGGRESSION	1	1									
				12. GLOBAL EVALUATION	1	1									
				11.Total score	12	12									
				461	Imipramine	Female	01. FACIAL EXPRESSION	1	1						
							02. BODY GESTURES	2	1						
							03. LOOK	1	1						
							04. OUTWARD APPEARANCE	2	2						
							05. SPEECH	2	2						
							06. VOICE	1	1						
07. ADAPTABILITY, SUGGESTIBILITY	1	1													
08. CONTACTS, AFFECTIVE NEED	2	1													
09. ANGUISH, ANXIETY	1	2													
10. AGGRESSION, IRRITABILITY	2	2													
11. SELF-AGGRESSION	1	1													
12. GLOBAL EVALUATION	2	2													
11.Total score	18	17													
462	Imipramine	Female	01. FACIAL EXPRESSION	2	1										
			02. BODY GESTURES	1	1										
			03. LOOK	1	0										
			04. OUTWARD APPEARANCE	2	1										
			05. SPEECH	2	1										
			06. VOICE	1	1										
			07. ADAPTABILITY, SUGGESTIBILITY	1	1										
			08. CONTACTS, AFFECTIVE NEED	1	2										
			09. ANGUISH, ANXIETY	1	1										
			10. AGGRESSION, IRRITABILITY	1	1										
			11. SELF-AGGRESSION	2	2										
			12. GLOBAL EVALUATION	15	12										
11.Total score	15	12													
4/1	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	2	2	2	2	1				
			02. BODY GESTURES	2	1	2	2	2	2	2	0				
			03. LOOK	1	1	1	1	1	1	1	0				
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	1				
			05. SPEECH	2	2	2	2	2	2	2	1				
			06. VOICE	2	2	2	2	2	2	2	1				
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	2	2	2	2	2	1				
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2	2				
			09. ANGUISH, ANXIETY	2	1	2	2	2	2	2	0				
			10. AGGRESSION, IRRITABILITY	3	2	3	3	3	3	3	1				
			11. SELF-AGGRESSION	1	1	1	1	1	1	1	1				
			12. GLOBAL EVALUATION	21	16	21	21	21	21	19	8				
11.Total score	21	16	21	21	21	19	8								

1424

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29

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
4/1	92	Reboxetine	Female	01.FACIAL EXPRESSION	3	3	3	3	3	3	3	3
				02.BODY GESTURES	3	3	3	3	3	3	3	
				03.LOOK	4	4	4	3	3	3	3	
				04.OUTWARD APPEARANCE	2	3	3	3	2	2	2	
				05.SPEECH	3	3	3	3	3	3	3	
				06.VOICE	3	4	4	3	3	3	2	
				07.ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	3	3	2	
				08.CONTACTS, AFFECTIVE NEED	3	3	3	3	3	3	3	
				09.ANGUISH, ANXIETY	3	3	3	3	3	3	3	
				10.AGRESSION, IRRITABILITY	2	2	2	3	2	2	2	
				11.SELF-AGGRESSION	4	4	4	3	3	3	3	
12.GLOBAL EVALUATION	3	3	3	3	3	3	3					
11.Total score	36	38	38	36	34	32	32					
1425	93	Placebo	Male	01.FACIAL EXPRESSION	1	1	2	1	0	0	0	
				02.BODY GESTURES	1	1	2	1	1	1	1	
				03.LOOK	2	2	2	1	0	0	0	
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	0	
				05.SPEECH	2	2	2	2	0	0	0	
				06.VOICE	1	1	3	1	0	0	0	
				07.ADAPTABILITY, SUGGESTIBILITY	0	0	1	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	1	1	2	2	1	1	1	
				09.ANGUISH, ANXIETY	1	1	1	2	0	0	0	
				10.AGRESSION, IRRITABILITY	4	0	0	1	0	0	0	
				11.SELF-AGGRESSION	0	0	1	1	1	1	1	
12.GLOBAL EVALUATION	1	1	2	2	0	0	0					
11.Total score	14	10	18	15	4	4	3					
94	94	Placebo	Female	01.FACIAL EXPRESSION	2	1	1	0	0	0	0	
				02.BODY GESTURES	2	2	1	1	1	1	1	
				03.LOOK	3	2	1	1	1	1	1	
				04.OUTWARD APPEARANCE	1	1	1	0	0	0	0	
				05.SPEECH	3	2	2	2	1	1	1	
				06.VOICE	2	2	1	1	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	2	1	1	0	2	1	1	
				09.ANGUISH, ANXIETY	2	1	1	0	0	0	0	
				10.AGRESSION, IRRITABILITY	1	1	1	0	0	0	0	
				11.SELF-AGGRESSION	2	1	1	1	1	1	1	
12.GLOBAL EVALUATION	2	2	1	1	0	0	0					
11.Total score	24	17	14	9	9	8	6					
95	95	Imipramine	Female	01.FACIAL EXPRESSION	2	1	1	1	1	0	0	
				02.BODY GESTURES	2	1	1	1	1	0	0	
				03.LOOK	2	0	0	0	0	0	0	
				04.OUTWARD APPEARANCE	1	1	1	1	0	0	0	
				05.SPEECH	2	1	1	1	1	0	0	

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centro	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	95	Imipramine	Female	06.VOICE	3	1	1	1	0	0	0
				07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	1	0	0	0	0	0	
				09.ANGUISH, ANXIETY	2	1	1	1	1	0	
				10.AGRESSION, IRRITABILITY	1	0	0	0	0	0	
				11.SELF-AGGRESSION	2	0	0	0	0	0	
				12.GLOBAL EVALUATION	2	1	1	1	0	0	
				11.Total score	22	8	8	8	3	1	
				01.FACIAL EXPRESSION	2	1	1	1	0	0	
				02.BODY GESTURES	2	1	1	1	0	0	
				03.LOOK	2	1	1	1	0	0	
				04.OUTWARD APPEARANCE	1	1	1	1	0	0	
05.SPEECH	3	2	1	1	0	0					
06.VOICE	2	1	1	1	0	0					
07.ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1					
08.CONTACTS, AFFECTIVE NEED	3	2	1	1	1	1					
09.ANGUISH, ANXIETY	2	2	1	1	1	1					
10.AGRESSION, IRRITABILITY	2	2	2	1	1	1					
11.SELF-AGGRESSION	2	2	1	1	1	1					
12.GLOBAL EVALUATION	2	2	1	1	1	1					
11.Total score	26	18	13	12	8	8					
115	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	2	2	1	1	1	1
			02.BODY GESTURES	1	1	1	1	1	0	0	
			03.LOOK	2	1	1	1	1	0	0	
			04.OUTWARD APPEARANCE	2	1	1	1	1	0	0	
			05.SPEECH	2	2	2	1	1	1		
			06.VOICE	2	2	2	1	1	1		
			07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1		
			08.CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1		
			09.ANGUISH, ANXIETY	2	2	2	1	1	1		
			10.AGRESSION, IRRITABILITY	2	2	2	1	1	1		
			11.SELF-AGGRESSION	2	1	1	1	1	1		
			12.GLOBAL EVALUATION	2	2	2	1	1	1		
11.Total score	23	20	20	11	10	8					
116	Imipramine	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2	2
			02.BODY GESTURES	1	1	1	1	1	1		
			03.LOOK	2	2	2	2	2	2		
			04.OUTWARD APPEARANCE	2	2	2	2	2	2		
			05.SPEECH	1	1	1	1	1	1		
			06.VOICE	1	1	1	1	1	1		
			07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1		
			08.CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2		
			09.ANGUISH, ANXIETY	3	3	3	3	3	3		
			10.AGRESSION, IRRITABILITY	2	2	2	2	2	2		
			11.SELF-AGGRESSION	2	2	2	2	2	2		
			12.GLOBAL EVALUATION	1	1	1	1	1	1		

9550082

31

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	116	Imipramine	Female	11. Total score	21	21					
	117	Imipramine	Female	01. FACIAL EXPRESSION	3	2	1	0	0	0	0
				02. BODY GESTURES	2	2	1	1	1	1	0
				03. LOOK	2	1	1	1	1	1	1
				04. OUTWARD APPEARANCE	2	1	1	1	1	1	1
				05. SPEECH	3	2	1	1	1	0	0
				06. VOICE	3	2	1	1	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	3	2	1	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	3	2	1	1	1	1	0
				09. ANGUISH, ANXIETY	2	1	1	1	1	1	0
				10. AGGRESSION, IRRITABILITY	2	1	1	1	1	1	0
				11. SELF-AGGRESSION	3	2	1	1	1	1	0
				12. GLOBAL EVALUATION	2	2	1	1	1	1	0
				11. Total score	30	20	12	11	10	7	3
	118	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	1	0	0	0
				02. BODY GESTURES	1	1	1	1	1	1	1
				03. LOOK	1	0	0	0	0	0	0
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	1
				05. SPEECH	2	2	1	1	1	1	1
				06. VOICE	1	1	1	1	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1
				09. ANGUISH, ANXIETY	2	2	2	1	1	1	1
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1
				11. SELF-AGGRESSION	2	1	1	1	1	1	1
				12. GLOBAL EVALUATION	2	2	2	1	1	1	1
				11. Total score	17	15	14	10	7	7	7
	119	Placebo	Female	01. FACIAL EXPRESSION	2						
				02. BODY GESTURES	2						
				03. LOOK	2						
				04. OUTWARD APPEARANCE	0						
				05. SPEECH	2						
				06. VOICE	1						
				07. ADAPTABILITY, SUGGESTIBILITY	2						
				08. CONTACTS, AFFECTIVE NEED	1						
				09. ANGUISH, ANXIETY	2						
				10. AGGRESSION, IRRITABILITY	2						
				11. SELF-AGGRESSION	1						
				12. GLOBAL EVALUATION	2						
				11. Total score	19						
	120	Placebo	Female	01. FACIAL EXPRESSION	2	2	1	0	0	0	0
				02. BODY GESTURES	1	1	0	0	0	0	0
				03. LOOK	1	1	1	0	0	0	0
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	1

1427

9550082

32

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
4/1	120	Placebo	Female	05. SPEECH	2	1	1	1	1	0	0	0			
				06. VOICE	1	1	0	0	0	0	0				
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	1				
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1				
				09. ANGUISH, ANXIETY	2	2	1	1	1	1	1				
				10. AGGRESSION, IRRITABILITY	2	1	2	1	1	1	1				
				11. SELF-AGGRESSION	1	1	1	1	1	1	1				
				12. GLOBAL EVALUATION	2	2	1	1	1	1	1				
				11. Total score	18	15	11	8	8	7	7				
				145	Imipramine	Female	01. FACIAL EXPRESSION	2	1	1	1	1	0	0	0
							02. BODY GESTURES	2	1	1	1	1	1	1	
							03. LOOK	1	1	1	1	0	0	0	
04. OUTWARD APPEARANCE	2	1	1				1	1	1	1					
05. SPEECH	2	1	1				1	1	1	1					
06. VOICE	1	1	1				1	1	1	1					
07. ADAPTABILITY, SUGGESTIBILITY	2	1	1				1	1	1	1					
08. CONTACTS, AFFECTIVE NEED	2	1	1				1	1	1	1					
09. ANGUISH, ANXIETY	3	2	2				1	1	1	1					
10. AGGRESSION, IRRITABILITY	3	2	2				1	1	1	1					
11. SELF-AGGRESSION	2	1	1				1	1	1	1					
12. GLOBAL EVALUATION	3	2	2				1	1	1	1					
11. Total score	25	15	15	12	10	10	8								
146	Placebo	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1				
			02. BODY GESTURES	2	1	1	1	1	1	1					
			03. LOOK	2	1	1	0	0	0	0					
			04. OUTWARD APPEARANCE	2	2	1	1	1	1	1					
			05. SPEECH	3	2	1	1	1	1	1					
			06. VOICE	2	2	2	1	1	1	1					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	1	1					
			08. CONTACTS, AFFECTIVE NEED	3	2	2	1	1	1	1					
			09. ANGUISH, ANXIETY	3	2	2	1	1	1	1					
			10. AGGRESSION, IRRITABILITY	2	2	2	1	1	1	1					
			11. SELF-AGGRESSION	2	1	1	1	1	1	1					
			12. GLOBAL EVALUATION	3	2	1	1	1	1	1					
11. Total score	27	20	16	11	11	10	8								
147	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	1	1	1	1	1				
			02. BODY GESTURES	2	1	1	1	1	1	1					
			03. LOOK	2	1	1	1	1	1	1					
			04. OUTWARD APPEARANCE	2	2	1	1	1	1	1					
			05. SPEECH	2	1	1	1	1	1	1					
			06. VOICE	2	1	1	1	1	1	1					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1	1					
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1					
			09. ANGUISH, ANXIETY	1	1	1	1	1	1	1					
			10. AGGRESSION, IRRITABILITY	2	2	1	1	1	1	1					
			11. SELF-AGGRESSION	1	1	1	1	1	1	1					

1428

9550082

33

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	147	Reboxetine	Female	12. GLOBAL EVALUATION	3	2	2	1	1	1	1
				11. Total score	23	16	13	12	12	11	11
				01. FACIAL EXPRESSION	2	2	1	1	1	1	1
				02. BODY GESTURES	2	1	1	1	1	1	1
				03. LOOK	2	1	1	0	0	1	1
				04. OUTWARD APPEARANCE	2	1	1	1	1	1	0
				05. SPEECH	2	1	1	1	1	0	1
				06. VOICE	1	1	1	1	1	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2
				09. ANGUISH, ANXIETY	2	2	1	1	1	1	1
				10. AGGRESSION, IRRITABILITY	2	1	1	1	1	1	1
11. SELF-AGGRESSION	2	1	1	1	1	1	1				
12. GLOBAL EVALUATION	2	2	2	1	1	1	1				
11. Total score	23	17	13	12	12	9	10				
149	149	Reboxetine	Male	01. FACIAL EXPRESSION	2	2	2	1	1	1	0
				02. BODY GESTURES	2	2	2	1	1	1	0
				03. LOOK	1	1	1	1	0	0	0
				04. OUTWARD APPEARANCE	2	2	1	1	1	0	1
				05. SPEECH	2	2	2	0	1	0	0
				06. VOICE	1	1	1	1	1	1	0
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	1
				09. ANGUISH, ANXIETY	2	2	2	2	1	1	1
				10. AGGRESSION, IRRITABILITY	2	2	2	2	1	1	1
				11. SELF-AGGRESSION	2	2	2	2	1	1	1
				12. GLOBAL EVALUATION	2	2	2	1	1	1	1
11. Total score	21	21	19	12	12	9	7				
150	150	Placebo	Male	01. FACIAL EXPRESSION	2	1	1	1	1	1	1
				02. BODY GESTURES	2	1	1	1	1	1	1
				03. LOOK	1	0	0	0	0	0	0
				04. OUTWARD APPEARANCE	2	1	0	1	1	1	0
				05. SPEECH	1	1	1	1	1	1	0
				06. VOICE	1	1	0	1	1	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	2	1	1	1
				08. CONTACTS, AFFECTIVE NEED	2	2	1	2	1	1	1
				09. ANGUISH, ANXIETY	2	2	1	2	1	1	1
				10. AGGRESSION, IRRITABILITY	1	1	2	1	1	1	1
				11. SELF-AGGRESSION	1	1	1	1	1	1	1
				12. GLOBAL EVALUATION	2	1	1	1	1	1	1
11. Total score	19	15	10	14	9	9	9				
4/2	95/A	Placebo	Male	01. FACIAL EXPRESSION	3	3	2	1	1	0	0
				02. BODY GESTURES	3	3	2	1	1	0	0
				03. LOOK	2	2	2	1	1	0	0

9550082

34

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/2	99/A	Placebo	Male	04. OUTWARD APPEARANCE	2	2	2	1	1	0	0
				05. SPEECH	3	3	2	1	1	0	
				06. VOICE	2	2	2	1	1	0	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	0	
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	0	0	
				09. ANGUISH, ANXIETY	3	3	2	1	1	0	
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	0	
				11. SELF-AGGRESSION	1	1	1	1	1	0	
				12. GLOBAL EVALUATION	2	2	2	1	1	0	
				11..Total score	26	26	22	12	10	1	
				01. FACIAL EXPRESSION	2	2	1	1	1	0	
				02. BODY GESTURES	3	3	2	2	1	0	
03. LOOK	2	2	1	1	1	0					
04. OUTWARD APPEARANCE	1	1	1	1	1	0					
05. SPEECH	2	2	1	1	1	0					
06. VOICE	2	2	1	1	1	0					
07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	0					
08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	0					
09. ANGUISH, ANXIETY	2	2	1	1	1	0					
10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0					
11. SELF-AGGRESSION	1	1	1	1	1	0					
12. GLOBAL EVALUATION	2	2	2	1	1	0					
11..Total score	21	21	12	12	10	0					
104	Reboxetine	Male	01. FACIAL EXPRESSION	3	3	3	2	2	2	2	2
			02. BODY GESTURES	2	2	2	2	2	2		
			03. LOOK	2	2	2	2	2	2		
			04. OUTWARD APPEARANCE	2	2	2	2	2	2		
			05. SPEECH	2	2	2	2	2	2		
			06. VOICE	1	1	1	1	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	2	2	2		
			08. CONTACTS, AFFECTIVE NEED	2	2	3	2	2	2		
			09. ANGUISH, ANXIETY	3	3	2	2	2	2		
			10. AGGRESSION, IRRITABILITY	2	2	2	2	1	1		
			11. SELF-AGGRESSION	1	1	1	1	1	1		
			12. GLOBAL EVALUATION	2	2	2	2	2	2		
11..Total score	26	26	26	22	21	21					
4/3	97	Placebo	Male	01. FACIAL EXPRESSION	1	0	0	0	1	1	1
				02. BODY GESTURES	1	1	1	1	1	1	
				03. LOOK	0	0	1	1	1	1	
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	
				05. SPEECH	1	1	1	1	1	1	
				06. VOICE	1	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	1	1	1	2	2	2	
				09. ANGUISH, ANXIETY	2	2	2	2	2	2	
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	
				11. SELF-AGGRESSION	2	2	2	2	2	2	
				12. GLOBAL EVALUATION	1	1	1	1	1	1	
11..Total score	26	26	26	22	21	21					

1430

9550082

35

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/3	97	Placebo	Male	11.SELF-AGGRESSION	0	1	1	1	1	1	1
				12.GLOBAL EVALUATION	2	2	2	2	2	2	
				11.Total score	11	13	13	14	15	16	
98	Reboxetine	Female	01.FACIAL EXPRESSION	1	2	2	1	1	1	2	2
			02.BODY GESTURES	1	2	2	1	1	1	2	
			03.LOOK	1	1	1	1	1	1	2	
			04.OUTWARD APPEARANCE	1	1	1	1	1	1	2	
			05.SPEECH	1	1	1	1	1	1	2	
			06.VOICE	1	1	1	1	1	1	2	
			07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	1	2	
			08.CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	2	
			09.ANGUISH, ANXIETY	2	2	2	1	1	1	2	
			10.AGRESSION, IRRITABILITY	2	1	1	1	1	1	2	
			11.SELF-AGGRESSION	1	1	1	1	1	1	2	
			12.GLOBAL EVALUATION	2	2	2	2	1	1	2	
11.Total score	17	18	18	12	12	12	24				
99	Placebo	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2	2
			02.BODY GESTURES	2	2	2	2	2	2	2	
			03.LOOK	1	1	1	1	1	1	2	
			04.OUTWARD APPEARANCE	2	2	2	2	2	2	2	
			05.SPEECH	2	2	2	2	2	2	2	
			06.VOICE	2	2	2	2	2	2	2	
			07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2	
			08.CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2	
			09.ANGUISH, ANXIETY	2	2	2	2	2	2	2	
			10.AGRESSION, IRRITABILITY	2	2	2	2	2	2	2	
			11.SELF-AGGRESSION	1	1	1	1	1	1	2	
			12.GLOBAL EVALUATION	2	2	2	2	2	2	2	
11.Total score	21	23	22	22	22	22	22				
100	Imipramine	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2	2
			02.BODY GESTURES	2	2	2	2	2	2	2	
			03.LOOK	2	1	1	1	1	1	2	
			04.OUTWARD APPEARANCE	2	2	2	2	2	2	2	
			05.SPEECH	2	1	1	1	1	1	2	
			06.VOICE	1	1	1	1	1	1	2	
			07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	2	
			08.CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2	
			09.ANGUISH, ANXIETY	2	2	2	2	2	2	2	
			10.AGRESSION, IRRITABILITY	1	1	1	1	1	1	2	
			11.SELF-AGGRESSION	1	1	1	1	1	1	2	
			12.GLOBAL EVALUATION	2	2	2	2	2	2	2	
11.Total score	21	17	19	19	19	19	19				
101	Imipramine	Male	01.FACIAL EXPRESSION	2	2	2	1	1	1	1	0
			02.BODY GESTURES	2	2	2	1	1	1	0	

1431

9550082

36

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/3	101	Imipramine	Male	03. LOOK	2	2	1	1	0	0	0
				04. OUTWARD APPEARANCE	2	2	1	1	0	0	0
				05. SPEECH	2	2	1	1	0	0	0
				06. VOICE	2	2	1	1	0	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	0	0	0
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	0	0	0
				09. ANGUISH, ANXIETY	2	2	2	1	0	0	0
				10. AGGRESSION, IRRITABILITY	2	2	1	1	0	0	0
				11. SELF-AGGRESSION	1	1	1	0	0	0	0
				12. GLOBAL EVALUATION	2	2	2	2	1	1	0
				11.Total score	23	23	15	12	4	3	2
4/4	109	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	0	0	0	0
				02. BODY GESTURES	1	1	1	0	0	0	0
				03. LOOK	1	1	1	0	0	0	0
				04. OUTWARD APPEARANCE	1	0	0	0	0	0	0
				05. SPEECH	2	2	1	1	0	0	0
				06. VOICE	2	2	1	1	0	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	0	0	0
				08. CONTACTS, AFFECTIVE NEED	2	2	1	0	0	0	0
				09. ANGUISH, ANXIETY	2	2	1	1	1	1	0
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0
				11. SELF-AGGRESSION	1	0	0	0	0	0	0
				12. GLOBAL EVALUATION	2	2	1	0	0	0	0
				11.Total score	18	13	9	4	2	1	0
	110	Imipramine	Male	01. FACIAL EXPRESSION	2	1	2	1	1	1	1
				02. BODY GESTURES	2	2	2	1	1	1	1
				03. LOOK	2	1	1	1	1	1	1
				04. OUTWARD APPEARANCE	2	2	2	1	1	1	1
				05. SPEECH	2	2	2	1	1	1	1
				06. VOICE	3	2	2	1	0	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	1
				09. ANGUISH, ANXIETY	2	2	2	1	1	1	1
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0
				11. SELF-AGGRESSION	1	1	1	0	0	0	0
				12. GLOBAL EVALUATION	2	2	2	1	1	1	1
				11.Total score	22	15	20	10	5	5	10
	111	Imipramine	Male	01. FACIAL EXPRESSION	3	2	1	1	1	0	0
				02. BODY GESTURES	2	3	2	1	1	1	0
				03. LOOK	2	2	1	1	0	0	0
				04. OUTWARD APPEARANCE	2	2	2	1	1	1	0
				05. SPEECH	3	3	2	2	1	0	0
				06. VOICE	3	3	2	2	1	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	3	3	2	2	1	1	1
				08. CONTACTS, AFFECTIVE NEED	3	3	2	2	1	1	1
				09. ANGUISH, ANXIETY	2	2	2	1	1	1	1

1432

9550082

37

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	RELATIONAL DEPRESSION RATING SCALE										
					Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
4/4	111	Imipramine	Male	10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0	0	0		
				11. SELF-AGGRESSION	0	0	0	0	0	0	0	0	0		
				12. GLOBAL EVALUATION	2	2	2	1	1	1	1				
				11. Total score	25	25	18	12	9	6	4				
				112	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	1	1	1	2	1
							02. BODY GESTURES	2	1	1	1	1	1	1	
							03. LOOK	1	1	1	1	1	1	1	
							04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	
							05. SPEECH	2	1	1	1	1	2	2	
							06. VOICE	4	1	1	1	1	2	2	
							07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1	1	
							08. CONTACTS, AFFECTIVE NEED	2	1	1	1	1	1	1	
09. ANGUISH, ANXIETY	1	1	1				1	1	1	1					
10. AGGRESSION, IRRITABILITY	1	1	1				0	0	0	0					
11. SELF-AGGRESSION	1	1	1				1	0	0	0					
12. GLOBAL EVALUATION	2	1	1				1	1	2	2					
11. Total score	17	13	12	10	10	14	13								
1433	113	Reboxetine	Male	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1			
				02. BODY GESTURES	2	2	1	1	1	1	0				
				03. LOOK	1	1	1	1	1	1	0				
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	0				
				05. SPEECH	2	2	2	1	1	1	1				
				06. VOICE	2	2	2	1	1	1	0				
				07. ADAPTABILITY, SUGGESTIBILITY	1	2	2	1	1	1	0				
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	0				
				09. ANGUISH, ANXIETY	2	2	2	1	1	1	1				
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0				
				11. SELF-AGGRESSION	4	0	0	0	0	0	0				
				12. GLOBAL EVALUATION	2	2	2	1	1	1	0				
11. Total score	21	18	15	10	10	6	3								
114	Placebo	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	0				
			02. BODY GESTURES	1	1	1	1	1	1	1					
			03. LOOK	2	1	1	1	0	0	0					
			04. OUTWARD APPEARANCE	2	1	1	1	1	0	0					
			05. SPEECH	1	1	1	1	1	1	0					
			06. VOICE	1	1	1	1	1	1	0					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	0	0					
			08. CONTACTS, AFFECTIVE NEED	2	2	1	1	0	0	0					
			09. ANGUISH, ANXIETY	2	2	2	1	1	1	1					
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0					
			11. SELF-AGGRESSION	1	1	0	0	0	0	0					
			12. GLOBAL EVALUATION	2	1	1	1	1	1	0					
11. Total score	19	15	11	10	8	6	2								
175	113	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	1	0	0				
				11. Total score	2	2	1	1	1	0	0				

9550082

58

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/4	175	Imipramine	Female	02. BODY GESTURES	2	2	1	1	0	0	0
				03. LOOK	2	2	0	0	0	0	
				04. OUTWARD APPEARANCE	2	1	0	0	0	0	
				05. SPEECH	2	2	1	1	0	0	
				06. VOICE	2	1	1	1	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	0	0	
				08. CONTACTS, AFFECTIVE NEED	2	1	1	1	0	0	
				09. ANGUISH, ANXIETY	2	2	1	1	1	0	
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	
				11. SELF-AGGRESSION	0	0	0	0	0	0	
				12. GLOBAL EVALUATION	2	2	1	1	0	0	
				11. Total score	19	16	8	8	2	2	
				176	176	Placebo	Female	01. FACIAL EXPRESSION	2	2	1
02. BODY GESTURES	1	1	1					1	2	2	
03. LOOK	1	1	1					1	2	2	
04. OUTWARD APPEARANCE	1	1	1					1	2	2	
05. SPEECH	2	1	1					1	2	2	
06. VOICE	1	1	1					1	2	2	
07. ADAPTABILITY, SUGGESTIBILITY	1	1	1					1	1	1	
08. CONTACTS, AFFECTIVE NEED	1	1	1					1	2	2	
09. ANGUISH, ANXIETY	2	2	2					2	0	0	
10. AGGRESSION, IRRITABILITY	0	0	0					0	0	0	
11. SELF-AGGRESSION	1	1	1					1	4	4	
12. GLOBAL EVALUATION	1	1	1					1	2	2	
11. Total score	13	12	11					11	23	23	
177	177	Imipramine	Female	01. FACIAL EXPRESSION	1	2	1	1	1	1	
				02. BODY GESTURES	1	1	1	1	1	1	
				03. LOOK	2	2	1	1	1	1	
				04. OUTWARD APPEARANCE	2	2	2	2	2	2	
				05. SPEECH	2	2	2	2	2	2	
				06. VOICE	1	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	
				09. ANGUISH, ANXIETY	0	1	1	1	1	1	
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	
				11. SELF-AGGRESSION	0	0	0	0	0	0	
				12. GLOBAL EVALUATION	2	2	1	1	1	1	
				11. Total score	17	20	14	14	0	0	
178	178	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	0	0	0	
				02. BODY GESTURES	2	1	1	0	1	0	
				03. LOOK	2	1	0	0	0	0	
				04. OUTWARD APPEARANCE	1	1	1	0	0	0	
				05. SPEECH	2	2	0	0	1	0	
				06. VOICE	2	1	0	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	0	0	
				08. CONTACTS, AFFECTIVE NEED	2	1	0	0	0	0	

1434

9550082

39

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
4/4	178	Reboxetine	Female	09. ANGUISH, ANXIETY	2	1	0	1	1	1	0				
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0				
				11. SELF-AGGRESSION	0	0	0	0	0	0					
				12. GLOBAL EVALUATION	2	1	0	0	0	0					
				11.Total score	18	11	3	1	3	1					
				179	Placebo	Female	01.FACIAL EXPRESSION	2	1	1	2	2	2	2	2
							02.BODY GESTURES	2	2	1	1	2	2		
							03.LOOK	2	2	2	2	2	2		
							04. OUTWARD APPEARANCE	2	2	1	2	2	2		
							05.SPEECH	2	1	1	2	2	2		
							06.VOICE	1	1	1	2	2	2		
							07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	2	2	2		
08.CONTACTS, AFFECTIVE NEED	2	2	2				2	2	2						
09.ANGUISH, ANXIETY	2	2	1				3	2	2						
10.AGRESSION, IRRITABILITY	2	2	0				0	0	0						
11.SELF-AGGRESSION	1	1	1				3	1	1						
12.GLOBAL EVALUATION	2	2	2				2	3	2						
11.Total score	19	17	14	25	14	25									
180	Reboxetine	Male	01.FACIAL EXPRESSION	2	2	1	0	0	0	0	0				
			02.BODY GESTURES	1	2	1	1	1	1						
			03.LOOK	2	1	1	0	0	0						
			04. OUTWARD APPEARANCE	1	1	1	1	0	0						
			05.SPEECH	2	2	1	0	0	0						
			06.VOICE	1	1	1	0	0	0						
			07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	0	0						
			08.CONTACTS, AFFECTIVE NEED	2	2	1	1	1	0						
			09.ANGUISH, ANXIETY	2	2	1	1	1	0						
			10.AGRESSION, IRRITABILITY	0	0	0	0	0	0						
			11.SELF-AGGRESSION	0	0	0	0	0	0						
			12.GLOBAL EVALUATION	2	2	1	0	0	0						
11.Total score	16	16	10	5	3	1									
5/1	Reboxetine	Male	01.FACIAL EXPRESSION	4	2	2	2	2	2	2	2				
			02.BODY GESTURES	3	2	1	2	1	1	1					
			03.LOOK	3	2	2	1	2	2	2					
			04. OUTWARD APPEARANCE	1	0	0	0	0	0	0					
			05.SPEECH	3	2	1	1	2	1	2					
			06.VOICE	2	1	1	1	2	1	2					
			07.ADAPTABILITY, SUGGESTIBILITY	3	1	1	1	2	1	2					
			08.CONTACTS, AFFECTIVE NEED	3	1	1	2	2	2	2					
			09.ANGUISH, ANXIETY	1	1	1	1	0	1	1					
			10.AGRESSION, IRRITABILITY	0	0	0	0	0	1	0					
			11.SELF-AGGRESSION	2	1	1	1	0	2	1					
			12.GLOBAL EVALUATION	27	15	13	13	15	15						

1435

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40

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
5/1	128	Reboxetine	Female	01.FACIAL EXPRESSION	1	1	0	0	0	0	0	1
				02.BODY GESTURES	1	0	0	1	0	0	0	0
				03.LOOK	2	1	2	1	1	1	0	0
				04.OUTWARD APPEARANCE	2	0	0	1	0	0	0	0
				05.SPEECH	1	1	0	0	0	0	0	0
				06.VOICE	1	1	1	0	0	1	1	1
				07.ADAPTABILITY, SUGGESTIBILITY	1	0	0	0	0	0	0	0
				08.CONTACTS, AFFECTIVE NEED	2	1	1	1	1	1	1	1
				09.ANGUISH, ANXIETY	3	1	1	1	1	1	1	2
				10.AGRESSION, IRRITABILITY	1	0	1	1	0	1	1	1
				11.SELF-AGGRESSION	2	1	2	2	1	0	1	1
12.GLOBAL EVALUATION	2	1	0	0	0	0	0	0				
11.Total score	19	8	8	8	8	3	4	6				
129	129	Placebo	Male	01.FACIAL EXPRESSION	2	1	1	1	0	1	1	1
				02.BODY GESTURES	1	1	1	1	1	1	1	1
				03.LOOK	2	1	1	0	0	0	0	1
				04.OUTWARD APPEARANCE	2	1	1	0	0	0	0	0
				05.SPEECH	2	2	1	2	1	1	1	1
				06.VOICE	2	1	2	1	1	1	1	0
				07.ADAPTABILITY, SUGGESTIBILITY	2	0	0	1	1	0	0	1
				08.CONTACTS, AFFECTIVE NEED	2	1	1	1	1	0	1	2
				09.ANGUISH, ANXIETY	3	1	1	1	1	0	1	2
				10.AGRESSION, IRRITABILITY	3	1	0	0	0	0	0	0
				11.SELF-AGGRESSION	3	3	2	1	0	0	2	2
12.GLOBAL EVALUATION	2	1	2	1	0	1	1	1				
11.Total score	24	14	13	10	4	6	10	10				
130	130	Placebo	Male	01.FACIAL EXPRESSION	2	2	1	2	1	0	2	
				02.BODY GESTURES	1	1	1	2	1	0	1	
				03.LOOK	3	2	2	2	0	1	0	
				04.OUTWARD APPEARANCE	2	2	1	1	0	0	0	
				05.SPEECH	3	2	2	2	1	1	1	
				06.VOICE	2	1	1	1	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	1	0	1	
				08.CONTACTS, AFFECTIVE NEED	2	2	2	2	1	0	2	
				09.ANGUISH, ANXIETY	2	2	2	2	2	0	2	
				10.AGRESSION, IRRITABILITY	0	1	1	1	1	0	0	
				11.SELF-AGGRESSION	1	1	1	1	0	0	0	
12.GLOBAL EVALUATION	2	2	2	2	0	0	1					
11.Total score	22	20	15	21	6	4	11					
131	131	Isipramine	Female	01.FACIAL EXPRESSION	2	2	1	2	1	1	0	
				02.BODY GESTURES	2	1	1	2	1	1	1	
				03.LOOK	1	2	1	1	1	0	0	
				04.OUTWARD APPEARANCE	2	1	1	1	1	1	1	
				05.SPEECH	2	2	1	2	2	1	0	
				06.VOICE	2	2	1	2	1	0	0	
				07.ADAPTABILITY, SUGGESTIBILITY	3	3	2	1	1	1	1	

1436

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41

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
5/1	131	Imipramine	Female	08. CONTACTS, AFFECTIVE NEED	3	2	2	2	2	2	1				
				09. ANGUISH, ANXIETY	3	2	1	1	0	0	0				
				10. AGGRESSION, IRRITABILITY	1	1	0	0	0	0					
				11. SELF-AGGRESSION	1	1	1	0	0	0					
				12. GLOBAL EVALUATION	1	1	1	1	1	0					
				11. Total score	23	20	13	15	11	8	4				
				132	Imipramine	Male	01. FACIAL EXPRESSION	1	0	0	0	0	0	0	0
							02. BODY GESTURES	1	0	0	0	0	0	0	
							03. LOOK	1	0	0	0	0	0	0	
							04. OUTWARD APPEARANCE	0	0	0	0	0	0	0	
							05. SPEECH	2	0	0	0	0	0	0	
06. VOICE	2	0	0				0	0	0	0					
07. ADAPTABILITY, SUGGESTIBILITY	1	0	0				0	0	0	0					
08. CONTACTS, AFFECTIVE NEED	2	0	0				0	0	0	0					
09. ANGUISH, ANXIETY	1	0	0				0	0	0	0					
10. AGGRESSION, IRRITABILITY	2	0	0				0	0	0	0					
11. SELF-AGGRESSION	1	0	0				0	0	0	0					
12. GLOBAL EVALUATION	1	0	0	0	0	0	0								
11. Total score	15	0	0	0	0	0	0								
5/2	121	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	2	1	1	2				
				02. BODY GESTURES	1	1	1	1	1	1	2				
				03. LOOK	1	1	0	1	1	1	1				
				04. OUTWARD APPEARANCE	3	2	2	2	2	2	2				
				05. SPEECH	3	2	2	2	2	2	2				
				06. VOICE	1	2	1	1	2	1	2				
				07. ADAPTABILITY, SUGGESTIBILITY	1	2	2	1	1	1	2				
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	0	1	3				
				09. ANGUISH, ANXIETY	2	3	3	2	2	1	3				
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	1	2				
				11. SELF-AGGRESSION	2	1	1	1	1	1	2				
12. GLOBAL EVALUATION	2	2	1	2	2	2	2								
11. Total score	18	19	16	17	14	15	22								
125	Reboxetine	Male	01. FACIAL EXPRESSION	2	1	1	0	0	0	0	0				
			02. BODY GESTURES	3	1	1	0	1	1	0					
			03. LOOK	2	1	0	0	0	1	0					
			04. OUTWARD APPEARANCE	1	1	0	1	0	1	0					
			05. SPEECH	2	0	1	0	0	0	0					
			06. VOICE	0	0	0	0	0	0	0					
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	0	0	0	1	1					
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	0	1	1					
			09. ANGUISH, ANXIETY	2	3	0	1	1	1	1					
			10. AGGRESSION, IRRITABILITY	1	2	1	0	1	1	1					
			11. SELF-AGGRESSION	0	0	0	0	0	0	0					
12. GLOBAL EVALUATION	2	1	1	1	1	1	0								
11. Total score	18	12	6	3	4	7	4								

1437

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42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0
RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
5/3	133	Placebo	Male	01.FACIAL EXPRESSION	2	3	3				
				02.BODY GESTURES	2	2	3				
				03.LOOK	1	1	1				
				04.OUTWARD APPEARANCE	1	1	1				
				05.SPEECH	2	3	3				
				06.VOICE	1	1	1				
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1				
				08.CONTACTS, AFFECTIVE NEED	2	2	2				
				09.ANGUISH, ANXIETY	2	2	2				
				10.AGRESSION, IRRITABILITY	0	0	1				
				11.SELF-AGGRESSION	2	2	2				
				12.GLOBAL EVALUATION	2	2	2				
				11.Total score	18	20	22				
	134	Reboxetine	Female	01.FACIAL EXPRESSION	1	1	0	0	0	0	0
				02.BODY GESTURES	1	1	0	0	0	0	0
				03.LOOK	1	1	0	0	0	0	0
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05.SPEECH	2	1	0	0	0	0	0
				06.VOICE	1	1	0	0	0	0	0
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	0	1	0	0	0
				08.CONTACTS, AFFECTIVE NEED	1	1	0	0	0	0	0
				09.ANGUISH, ANXIETY	2	2	1	3	0	0	0
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0	0
				11.SELF-AGGRESSION	1	1	0	1	0	0	0
				12.GLOBAL EVALUATION	1	1	0	1	0	0	0
				11.Total score	12	11	1	7	0	0	0
	135	Imipramine	Female	01.FACIAL EXPRESSION	1	0	0	0	0	1	2
				02.BODY GESTURES	1	0	0	0	0	1	2
				03.LOOK	0	0	0	0	0	0	1
				04.OUTWARD APPEARANCE	1	0	0	0	0	0	0
				05.SPEECH	1	1	0	0	1	2	2
				06.VOICE	1	0	0	0	0	0	1
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	0	0	1
				08.CONTACTS, AFFECTIVE NEED	0	0	0	0	0	1	1
				09.ANGUISH, ANXIETY	1	1	0	0	1	2	1
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0	1
				11.SELF-AGGRESSION	0	0	0	0	0	0	0
				12.GLOBAL EVALUATION	0	0	0	0	0	0	1
				11.Total score	8	4	0	0	2	8	13
	136	Imipramine	Female	01.FACIAL EXPRESSION	2	1	0	0	0	0	0
				02.BODY GESTURES	1	0	0	0	1	0	0
				03.LOOK	1	0	0	0	0	0	0
				04.OUTWARD APPEARANCE	1	0	0	0	0	0	0
				05.SPEECH	2	1	0	0	0	0	0

1438

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43

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
5/3	156	Imipramine	Female	06.VOICE	1	1	0	0	0	0	0				
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	0	0					
				08.CONTACTS, AFFECTIVE NEED	1	1	0	0	0	0					
				09.ANGUISH, ANXIETY	1	2	1	0	0	0					
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0					
				11.SELF-AGGRESSION	0	0	0	0	0	0					
				12.GLOBAL EVALUATION	1	1	0	0	1	0					
				11.Total score	12	8	1	0	3	0					
				137	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	1	1	0	0	0	0
							02.BODY GESTURES	2	1	1	1	1	1		
							03.LOOK	1	0	0	0	0	0		
							04.OUTWARD APPEARANCE	1	1	0	0	0	0		
05.SPEECH	2	1	1				0	0	0						
06.VOICE	2	1	0				0	0	0						
07.ADAPTABILITY, SUGGESTIBILITY	2	1	0				0	0	0						
08.CONTACTS, AFFECTIVE NEED	2	2	1				0	0	0						
09.ANGUISH, ANXIETY	2	2	1				1	1	1						
10.AGRESSION, IRRITABILITY	1	0	0				0	0	0						
11.SELF-AGGRESSION	1	0	0				0	0	0						
12.GLOBAL EVALUATION	1	1	1				1	1	1						
11.Total score	19	12	6	2	2	2									
138	Placebo	Female	01.FACIAL EXPRESSION	1	1	1	1	1	1	1	1				
			02.BODY GESTURES	2	2	2	2	2	2						
			03.LOOK	0	0	0	0	0	0						
			04.OUTWARD APPEARANCE	1	1	1	1	1	1						
			05.SPEECH	1	1	1	1	1	1						
			06.VOICE	1	1	1	1	1	1						
			07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2						
			08.CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2						
			09.ANGUISH, ANXIETY	0	0	0	0	0	0						
			10.AGRESSION, IRRITABILITY	0	0	0	0	0	0						
			11.SELF-AGGRESSION	0	0	0	0	0	0						
			12.GLOBAL EVALUATION	1	1	1	1	1	1						
11.Total score	12	12	6	2	2	2									
6/1	Imipramine	Male	01.FACIAL EXPRESSION	2	2	2	2	2	2	2	2				
			02.BODY GESTURES	2	2	2	2	2	2						
			03.LOOK	1	1	1	1	1	1						
			04.OUTWARD APPEARANCE	2	2	2	2	2	2						
			05.SPEECH	3	3	3	3	3	3						
			06.VOICE	1	1	1	1	1	1						
			07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1						
			08.CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2						
			09.ANGUISH, ANXIETY	3	3	3	3	3	3						
			10.AGRESSION, IRRITABILITY	2	2	2	2	2	2						
			11.SELF-AGGRESSION	2	2	2	2	2	2						
			12.GLOBAL EVALUATION	2	2	2	2	2	2						

1439

9550082

44

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/1	151	Imipramine	Male	11. Total score	23	17					
	152	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	1	1	0	0
				02. BODY GESTURES	2	1	1	1	1	1	1
				03. LOOK	1	1	1	1	1	0	0
				04. OUTWARD APPEARANCE	1	0	0	0	0	0	0
				05. SPEECH	2	1	1	1	1	1	0
				06. VOICE	2	1	1	1	1	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	0	0
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	0	0	1
				09. ANGUISH, ANXIETY	2	2	1	0	0	0	0
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1
				11. SELF-AGGRESSION	2	1	1	1	1	1	0
				12. GLOBAL EVALUATION	2	1	1	1	1	0	0
				11. Total score	19	12	11	10	8	5	3
	153	Reboxetine	Male	01. FACIAL EXPRESSION	2	2	1	0	0	0	0
				02. BODY GESTURES	1	1	1	1	1	1	1
				03. LOOK	1	1	0	0	0	0	0
				04. OUTWARD APPEARANCE	1	1	1	0	0	0	0
				05. SPEECH	2	2	1	1	1	1	1
				06. VOICE	1	1	1	1	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	1
				09. ANGUISH, ANXIETY	2	1	1	0	0	0	0
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1
				11. SELF-AGGRESSION	2	1	1	1	1	1	1
				12. GLOBAL EVALUATION	2	1	1	1	1	1	1
				11. Total score	19	16	12	8	8	8	8
	154	Imipramine	Female	01. FACIAL EXPRESSION	1						
				02. BODY GESTURES	1						
				03. LOOK	1						
				04. OUTWARD APPEARANCE	0						
				05. SPEECH	1						
				06. VOICE	1						
				07. ADAPTABILITY, SUGGESTIBILITY	1						
				08. CONTACTS, AFFECTIVE NEED	0						
				09. ANGUISH, ANXIETY	2						
				10. AGGRESSION, IRRITABILITY	1						
				11. SELF-AGGRESSION	2						
				12. GLOBAL EVALUATION	1						
				11. Total score	12						
	155	Placebo	Male	01. FACIAL EXPRESSION	3	3	2	2	2		
				02. BODY GESTURES	2	2	2	2	2		
				03. LOOK	1	1	1	1	1		
				04. OUTWARD APPEARANCE	1	1	1	1	1		

1440

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45

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/1	155	Placebo	Male	05. SPEECH	3	3	2	2	2	2	
				06. VOICE	2	2	2	1	2		
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	2		
				08. CONTACTS, AFFECTIVE NEED	3	3	2	2	3		
				09. ANGUISH, ANXIETY	3	2	1	1	1		
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1		
				11. SELF-AGGRESSION	1	1	1	1	1		
				12. GLOBAL EVALUATION	2	2	2	2	2		
				11.Total score	24	23	18	17	20		
				01. FACIAL EXPRESSION	3	3	1	1	1	1	
				02. BODY GESTURES	2	2	1	1	0	1	
				03. LOOK	2	2	1	1	1	1	
04. OUTWARD APPEARANCE	4	4	1	0	1	0					
05. SPEECH	4	4	1	1	1	0					
06. VOICE	4	4	0	1	1	0					
07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1					
08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	0					
09. ANGUISH, ANXIETY	3	3	1	1	1	1					
10. AGGRESSION, IRRITABILITY	2	2	2	2	1	1					
11. SELF-AGGRESSION	0	1	0	1	1	0					
12. GLOBAL EVALUATION	2	2	1	1	1	0					
11.Total score	20	19	11	12	11	8					
6/2	157	Reboxetine	Male	01. FACIAL EXPRESSION	2	2	1	1	1	1	1
				02. BODY GESTURES	2	2	2	2	0	1	
				03. LOOK	2	2	3	2	2	1	
				04. OUTWARD APPEARANCE	1	2	1	2	2	2	
				05. SPEECH	2	2	2	1	1	1	
				06. VOICE	1	2	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	
				09. ANGUISH, ANXIETY	3	2	2	1	2	2	
				10. AGGRESSION, IRRITABILITY	1	2	1	2	1	1	
				11. SELF-AGGRESSION	2	1	1	1	1	1	
				12. GLOBAL EVALUATION	2	2	1	1	1	1	
11.Total score	22	23	19	16	15	13					
6/2	158	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	1	1	1	1
				02. BODY GESTURES	2	2	2	2	2	2	
				03. LOOK	1	2	1	1	1	1	
				04. OUTWARD APPEARANCE	1	1	1	1	1	0	
				05. SPEECH	2	2	2	2	1	0	
				06. VOICE	2	2	2	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	1	
				09. ANGUISH, ANXIETY	2	2	2	2	2	2	
				10. AGGRESSION, IRRITABILITY	2	2	2	1	1	1	
				11. SELF-AGGRESSION	1	1	1	1	1	1	
				11.Total score	1	1	1	1	1	0	

1441

9550082

46

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centro	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/2	158	Imipramine	Female	12.GLOBAL EVALUATION	2	2	2	1	2	2	0
				11.Total score	20	21	19	15	18	7	
				01.FACIAL EXPRESSION	1	1	1	1	0	0	
				02.BODY GESTURES	2	2	1	1	1	1	
				03.LOOK	1	1	1	1	1	1	
				04.OUTWARD APPEARANCE	0	0	0	1	0	0	
				05.SPEECH	2	1	2	1	1	1	
				06.VOICE	1	1	1	1	1	0	
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	0	0	
				08.CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	
				09.ANGUISH, ANXIETY	1	2	3	1	1	2	
				10.AGRESSION, IRRITABILITY	1	2	1	1	1	1	
11.SELF-AGGRESSION	1	1	2	0	1	1					
12.GLOBAL EVALUATION	1	1	1	1	1	1					
11.Total score	14	15	16	11	8	8					
1442	160	Placebo	Male	01.FACIAL EXPRESSION	2	1	1	1	1	1	1
				02.BODY GESTURES	2	1	1	1	1	1	
				03.LOOK	1	1	1	1	1	1	
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	
				05.SPEECH	1	1	1	1	1	1	
				06.VOICE	2	2	2	2	2	2	
				07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	2	
				08.CONTACTS, AFFECTIVE NEED	3	1	1	1	1	1	
				09.ANGUISH, ANXIETY	3	1	1	1	1	1	
				10.AGRESSION, IRRITABILITY	2	1	1	1	1	1	
				11.SELF-AGGRESSION	3	1	1	1	1	2	
				12.GLOBAL EVALUATION	2	1	1	1	1	1	
11.Total score	23	12	12	12	12	14					
	161	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	1	1	1	1	1
				02.BODY GESTURES	3	2	2	2	2	2	
				03.LOOK	2	2	2	2	2	2	
				04.OUTWARD APPEARANCE	2	2	2	1	1	1	
				05.SPEECH	2	2	2	2	2	2	
				06.VOICE	2	3	2	2	2	2	
				07.ADAPTABILITY, SUGGESTIBILITY	1	2	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	4	2	1	2	2	2	
				09.ANGUISH, ANXIETY	2	2	2	2	2	2	
				10.AGRESSION, IRRITABILITY	1	2	2	2	2	2	
				11.SELF-AGGRESSION	1	2	1	1	1	1	
				12.GLOBAL EVALUATION	1	2	1	2	2	2	
11.Total score	22	25	20	20	20	20					
	162	Placebo	Male	01.FACIAL EXPRESSION	3	3					
				02.BODY GESTURES	2	2					
				03.LOOK	1	1					

9550082

47

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS E&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/2	162	Placebo	Male	04. OUTWARD APPEARANCE	2	1					
				05. SPEECH	2	2					
				06. VOICE	1	1					
				07. ADAPTABILITY, SUGGESTIBILITY	2	2					
				08. CONTACTS, AFFECTIVE NEED	1	1					
				09. ANGUISH, ANXIETY	2	2					
				10. AGGRESSION, IRRITABILITY	1	1					
				11. SELF-AGGRESSION	1	1					
				12. GLOBAL EVALUATION	2	2					
				11.Total score	20	19					
				169	Imipramine	Female	01. FACIAL EXPRESSION	3	0	3	3
02. BODY GESTURES	2	0	2				2	2			
03. LOOK	3	0	3				3	3			
04. OUTWARD APPEARANCE	3	0	3				3	3			
05. SPEECH	3	0	3				3	3			
06. VOICE	2	0	2				2	2			
07. ADAPTABILITY, SUGGESTIBILITY	2	0	2				2	2			
08. CONTACTS, AFFECTIVE NEED	3	0	3				3	3			
09. ANGUISH, ANXIETY	2	0	2				2	2			
10. AGGRESSION, IRRITABILITY	3	0	3				3	3			
11. SELF-AGGRESSION	3	0	3				3	3			
12. GLOBAL EVALUATION	2	0	2	2	2						
11.Total score	30	0	33	36							
170	Placebo	Male	01. FACIAL EXPRESSION	3	1						
			02. BODY GESTURES	2	1						
			03. LOOK	4	0						
			04. OUTWARD APPEARANCE	3	0						
			05. SPEECH	3	0						
			06. VOICE	3	1						
			07. ADAPTABILITY, SUGGESTIBILITY	3	1						
			08. CONTACTS, AFFECTIVE NEED	3	1						
			09. ANGUISH, ANXIETY	3	1						
			10. AGGRESSION, IRRITABILITY	2	0						
			11. SELF-AGGRESSION	3	1						
12. GLOBAL EVALUATION	3	1									
11.Total score	35	8									
171	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	0	0	0	0	0
			02. BODY GESTURES	2	2	1	0	0	0		
			03. LOOK	2	2	1	0	0	0		
			04. OUTWARD APPEARANCE	2	2	0	0	0	0		
			05. SPEECH	2	2	1	0	0	0		
			06. VOICE	2	2	0	0	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	0	0	0	0		
			08. CONTACTS, AFFECTIVE NEED	2	2	1	0	0	0		
			09. ANGUISH, ANXIETY	2	2	1	0	0	0		
			10. AGGRESSION, IRRITABILITY	2	2	1	0	0	0		
			11.Total score	1	1	1	0	0	0		

1443

9550082

48

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PHARMACIA CNS R3D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
6/2	171	Imipramine	Female	11.SELF-AGGRESSION	2	2	0	0	0	0	0	
				12.GLOBAL EVALUATION	2	2	1	0	0	0	0	
				11.Total score	23	23	9	0	0	0	0	
	172	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	2	3	3	3	3	3
				02.BODY GESTURES	2	2	2	2	3	3	3	
				03.LOOK	2	2	2	2	2	2	3	
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	1	
				05.SPEECH	2	2	2	2	2	2	2	
				06.VOICE	2	2	2	2	2	2	2	
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2	
				08.CONTACTS, AFFECTIVE NEED	3	3	3	3	3	3	3	
				09.ANGUISH, ANXIETY	3	3	3	3	3	3	3	
10.AGRESSION, IRRITABILITY				0	0	1	1	1	2	2		
11.SELF-AGGRESSION				3	3	3	3	3	3	3		
12.GLOBAL EVALUATION				2	2	2	2	2	2	2		
11.Total score	25	25	26	26	28	28	34					
173	Placebo	Male	01.FACIAL EXPRESSION	2	2	2	2	2	3	1	1	
			02.BODY GESTURES	2	2	2	2	2	2	1		
			03.LOOK	2	2	2	2	3	1	1		
			04.OUTWARD APPEARANCE	2	2	2	2	2	1	1		
			05.SPEECH	2	2	2	2	3	1	1		
			06.VOICE	2	2	2	2	2	1	1		
			07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	1		
			08.CONTACTS, AFFECTIVE NEED	3	3	3	3	3	2	1		
			09.ANGUISH, ANXIETY	3	3	3	3	3	1	1		
			10.AGRESSION, IRRITABILITY	1	1	1	1	2	2	2		
			11.SELF-AGGRESSION	3	3	3	3	3	1	1		
			12.GLOBAL EVALUATION	2	2	2	2	3	2	2		
11.Total score	26	26	26	26	31	16	14					
174	Reboxetine	Male	01.FACIAL EXPRESSION	2	0	0	0	0	0	0	1	
			02.BODY GESTURES	2	1	0	0	0	0	1		
			03.LOOK	4	0	0	0	0	0	1		
			04.OUTWARD APPEARANCE	3	0	0	0	0	0	0		
			05.SPEECH	2	0	1	0	0	0	1		
			06.VOICE	2	1	0	0	0	0	1		
			07.ADAPTABILITY, SUGGESTIBILITY	2	0	0	0	0	0	1		
			08.CONTACTS, AFFECTIVE NEED	3	1	0	0	0	0	1		
			09.ANGUISH, ANXIETY	3	0	0	0	0	0	0		
			10.AGRESSION, IRRITABILITY	3	0	0	0	0	0	0		
			11.SELF-AGGRESSION	3	1	0	0	0	0	1		
			12.GLOBAL EVALUATION	2	0	0	0	0	0	2		
11.Total score	31	4	1	0	0	0	12					
6/3	163	Reboxetine	Male	01.FACIAL EXPRESSION	2	2						
				02.BODY GESTURES	2	2						

9550082

49

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
6/3	163	Reboxetine	Male	03. LOOK	1	1							
				04. OUTWARD APPEARANCE	1	1							
				05. SPEECH	2	2							
				06. VOICE	2	2							
				07. ADAPTABILITY, SUGGESTIBILITY	2	2							
				08. CONTACTS, AFFECTIVE NEED	2	2							
				09. ANGUISH, ANXIETY	3	3							
				10. AGGRESSION, IRRITABILITY	2	2							
				11. SELF-AGGRESSION	2	2							
				12. GLOBAL EVALUATION	2	2							
				11. Total score	23	23							
1445	164	Imipramine	Male	01. FACIAL EXPRESSION	1	2	2	2	1	1	1	0	
				02. BODY GESTURES	1	2	1	1	1	1	1		
				03. LOOK	2	2	2	2	1	1	1		
				04. OUTWARD APPEARANCE	1	1	0	1	1	1	1		
				05. SPEECH	1	1	1	1	1	1	1		
				06. VOICE	1	1	1	1	1	1	1		
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1	0		
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	1	1		
				09. ANGUISH, ANXIETY	1	2	1	1	1	1	1		
				10. AGGRESSION, IRRITABILITY	1	3	1	1	2	1	1		
				11. SELF-AGGRESSION	2	2	1	1	1	1	1		
12. GLOBAL EVALUATION	2	2	1	1	1	1	1						
11. Total score	19	22	14	15	15	12	8						
165	165	Imipramine	Female	01. FACIAL EXPRESSION	2	1	1	1	0	0	0		
				02. BODY GESTURES	2	1	1	1	1	1	1		
				03. LOOK	2	1	1	1	1	0	0		
				04. OUTWARD APPEARANCE	1	1	1	0	1	1	1		
				05. SPEECH	2	1	1	1	1	1	2		
				06. VOICE	1	1	1	1	0	1	1		
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	0	1	2		
				08. CONTACTS, AFFECTIVE NEED	3	1	1	1	1	2	1		
				09. ANGUISH, ANXIETY	2	1	1	1	1	2	2		
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	0		
				11. SELF-AGGRESSION	1	1	1	1	1	1	2		
12. GLOBAL EVALUATION	2	1	1	1	1	1	2						
11. Total score	21	12	12	11	9	13	1						
166	166	Reboxetine	Female	01. FACIAL EXPRESSION	2	3							
				02. BODY GESTURES	2	3							
				03. LOOK	1	1							
				04. OUTWARD APPEARANCE	2	1							
				05. SPEECH	2	3							
				06. VOICE	1	2							
				07. ADAPTABILITY, SUGGESTIBILITY	1	3							
				08. CONTACTS, AFFECTIVE NEED	2	3							
				09. ANGUISH, ANXIETY	2	3							

9550082

51

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	506	Placebo	Female	02. BODY GESTURES	1	2	2	2	2	1	2
				03. LOOK	2	2	2	2	1	0	1
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	1
				05. SPEECH	2	2	2	2	2	1	1
				06. VOICE	2	2	2	2	2	1	2
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	1	2
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	1	2
				09. ANGUISH, ANXIETY	2	2	2	2	2	1	2
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	0	0
				11. SELF-AGGRESSION	2	2	2	2	2	2	2
				12. GLOBAL EVALUATION	2	2	2	2	2	2	2
				11.Total score	21	23	23	19	16	13	18
507	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1
			02. BODY GESTURES	1	1	1	1	1	0	0	
			03. LOOK	2	1	1	1	1	0	0	
			04. OUTWARD APPEARANCE	1	1	0	0	1	0	0	
			05. SPEECH	2	2	2	2	1	0	1	
			06. VOICE	1	1	1	1	1	1	0	
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	1	2	
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	0	0	
			09. ANGUISH, ANXIETY	1	1	1	1	1	0	0	
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	2	1	
			11. SELF-AGGRESSION	2	2	2	2	2	1	1	
			12. GLOBAL EVALUATION	2	2	2	2	2	1	1	
11.Total score	20	18	16	11	15	6	6				
508	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	2	1	1	2	1	1
			02. BODY GESTURES	2	1	1	1	1	1	1	
			03. LOOK	2	2	1	1	1	1	1	
			04. OUTWARD APPEARANCE	1	1	1	1	1	0	0	
			05. SPEECH	2	2	2	2	2	1	1	
			06. VOICE	2	1	1	1	1	1	1	
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	2	2	2	1	2	
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2	
			09. ANGUISH, ANXIETY	1	1	2	0	1	1	0	
			10. AGGRESSION, IRRITABILITY	1	1	2	0	1	1	1	
			11. SELF-AGGRESSION	2	2	2	2	2	2	2	
			12. GLOBAL EVALUATION	2	2	2	2	2	2	2	
11.Total score	22	17	20	15	17	14	13				
509	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	2	1	1	1	1
			02. BODY GESTURES	1	1	1	1	1	1	1	
			03. LOOK	2	1	1	1	1	1	1	
			04. OUTWARD APPEARANCE	1	1	0	1	1	1	0	
			05. SPEECH	2	2	2	2	2	2	2	
			06. VOICE	1	1	1	1	1	1	1	
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2	

1447

9550082

52

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
6/3	503	Placebo	Male	09. ANGUISH, ANXIETY	2	1	1	1	1	1	1				
				10. AGGRESSION, IRRITABILITY	1	1	1	0	0	0	1				
				11. SELF-AGGRESSION	2	2	2	2	2	2	1				
				12. GLOBAL EVALUATION	2	2	2	2	2	2	2				
				11. Total score	19	16	15	16	15	15	14				
				510	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2					
							02. BODY GESTURES	2	1	1					
							03. LOOK	2	1	1					
							04. OUTWARD APPEARANCE	1	1	1					
							05. SPEECH	2	2	1					
							06. VOICE	1	2	1					
							07. ADAPTABILITY, SUGGESTIBILITY	2	2	1					
08. CONTACTS, AFFECTIVE NEED	2	2	2												
09. ANGUISH, ANXIETY	2	2	2												
10. AGGRESSION, IRRITABILITY	1	0	1												
11. SELF-AGGRESSION	2	2	1												
12. GLOBAL EVALUATION	2	2	2												
11. Total score	21	18	15												
1448	511	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	3				
				02. BODY GESTURES	1	1	1	1	1	1	1				
				03. LOOK	1	1	1	0	0	1	1				
				04. OUTWARD APPEARANCE	1	1	1	1	0	1	1				
				05. SPEECH	2	1	2	1	1	2	2				
				06. VOICE	1	1	1	1	1	1	1				
				07. ADAPTABILITY, SUGGESTIBILITY	1	2	1	1	1	1	1				
				08. CONTACTS, AFFECTIVE NEED	2	2	1	1	2	2	2				
				09. ANGUISH, ANXIETY	2	2	1	1	1	1	1				
				10. AGGRESSION, IRRITABILITY	1	1	0	0	0	1	2				
				11. SELF-AGGRESSION	1	2	1	1	1	2	3				
				12. GLOBAL EVALUATION	1	2	1	1	1	2	3				
11. Total score	17	18	11	10	13	21									
512	Placebo	Female	01. FACIAL EXPRESSION	1	1										
			02. BODY GESTURES	1	1										
			03. LOOK	1	1										
			04. OUTWARD APPEARANCE	1	1										
			05. SPEECH	2	2										
			06. VOICE	2	1										
			07. ADAPTABILITY, SUGGESTIBILITY	2	2										
			08. CONTACTS, AFFECTIVE NEED	2	2										
			09. ANGUISH, ANXIETY	1	1										
			10. AGGRESSION, IRRITABILITY	1	1										
			11. SELF-AGGRESSION	2	2										
			12. GLOBAL EVALUATION	2	2										
11. Total score	18	18													

9550082

53

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	513	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	1	0	1
				02. BODY GESTURES	1	1	1	1	1	1	1
				03. LOOK	1	1	1	0	0	0	1
				04. OUTWARD APPEARANCE	1	0	0	0	0	0	0
				05. SPEECH	2	2	1	1	1	1	0
				06. VOICE	1	1	1	1	1	1	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	0
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	1
				09. ANGUISH, ANXIETY	2	2	1	1	1	1	1
				10. AGGRESSION, IRRITABILITY	1	0	2	0	0	1	1
				11. SELF-AGGRESSION	2	2	2	2	1	1	1
				12. GLOBAL EVALUATION	2	2	2	2	1	1	1
11.Total score	19	16	15	9	9	8					
7/02	181	Reboxetine	Male	01. FACIAL EXPRESSION	2	2	2	1	1	1	1
				02. BODY GESTURES	1	1	1	1	1	1	1
				03. LOOK	2	2	1	2	1	1	1
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	1
				05. SPEECH	2	2	2	2	2	2	2
				06. VOICE	1	1	1	1	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1
				09. ANGUISH, ANXIETY	2	2	1	1	1	1	1
				10. AGGRESSION, IRRITABILITY	2	2	2	2	2	2	2
				11. SELF-AGGRESSION	0	0	0	0	0	0	0
				12. GLOBAL EVALUATION	2	2	2	2	2	2	
11.Total score	17	17	16	15	14	14					
182	182	Placebo	Male	01. FACIAL EXPRESSION	0	2	0	2	1	1	1
				02. BODY GESTURES	1	0	1	1	1	1	1
				03. LOOK	1	1	1	1	1	1	1
				04. OUTWARD APPEARANCE	0	1	0	1	1	1	1
				05. SPEECH	2	1	2	1	1	1	1
				06. VOICE	1	1	1	1	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	1	2	1	2	2	2	2
				09. ANGUISH, ANXIETY	3	2	2	2	1	1	1
				10. AGGRESSION, IRRITABILITY	1	1	1	1	2	0	1
				11. SELF-AGGRESSION	1	1	1	1	2	2	2
				12. GLOBAL EVALUATION	2	2	2	2	2	2	
11.Total score	14	15	13	17	16	14					
183	183	Imipramine	Male	01. FACIAL EXPRESSION	3	3	3	2	2	2	2
				02. BODY GESTURES	2	2	2	2	2	2	
				03. LOOK	1	1	1	1	1	1	
				04. OUTWARD APPEARANCE	2	2	2	2	2	3	
				05. SPEECH	2	2	2	2	2	2	
				06. VOICE	1	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	

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54

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PHARMACIA CNS R&D
 RENOXETINE - PROTOCOL 20124/015
 Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
7/02	183	Imipramine	Male	08. CONTACTS, AFFECTIVE NEED	2	2	2	1							
				09. ANGUISH, ANXIETY	2	1	2	3							
				10. AGGRESSION, IRRITABILITY	1	1	1	2							
				11. SELF-AGGRESSION	1	1	1	1							
				12. GLOBAL EVALUATION	2	2	2	2							
				11. Total score	20	19	20	21							
				184	Imipramine	Female	01. FACIAL EXPRESSION	3	3	2	1		1	0	0
							02. BODY GESTURES	2	2	2	1		1	1	1
							03. LOOK	1	1	1	1		1	0	0
							04. OUTWARD APPEARANCE	0	0	0	0		0	0	0
							05. SPEECH	3	3	2	1		0	0	0
							06. VOICE	1	1	1	1		1	1	1
07. ADAPTABILITY, SUGGESTIBILITY	1	1	1				1		1	1	1				
08. CONTACTS, AFFECTIVE NEED	2	2	2				1		1	1	1				
09. ANGUISH, ANXIETY	2	2	2				1		1	1	1				
10. AGGRESSION, IRRITABILITY	0	0	0				0		0	0	0				
11. SELF-AGGRESSION	2	2	1				1		1	1	1				
12. GLOBAL EVALUATION	2	2	1				1		1	1	1				
11. Total score	19	19	16	11		11	6	6							
1450	185	Roxoxetine	Male	01. FACIAL EXPRESSION	1	1	1	1		1	1				
				02. BODY GESTURES	1	1	1	1		1	1				
				03. LOOK	0	1	1	1		1	1				
				04. OUTWARD APPEARANCE	1	1	1	1		1	1				
				05. SPEECH	1	2	1	2		1	1				
				06. VOICE	1	1	1	1		1	1				
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1		1	1				
				08. CONTACTS, AFFECTIVE NEED	1	1	2	2		1	1				
				09. ANGUISH, ANXIETY	1	1	1	1		2	2				
				10. AGGRESSION, IRRITABILITY	2	2	1	1		2	2				
				11. SELF-AGGRESSION	2	2	2	2		2	2				
				12. GLOBAL EVALUATION	1	1	2	2		2	2				
11. Total score	12	14	15	16		16	16								
186	186	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	1		0	0				
				02. BODY GESTURES	1	1	1	1		1	1				
				03. LOOK	1	1	1	1		1	1				
				04. OUTWARD APPEARANCE	1	1	0	0		0	0				
				05. SPEECH	2	1	1	1		1	1				
				06. VOICE	1	1	1	1		1	1				
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1		1	1				
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1		1	1				
				09. ANGUISH, ANXIETY	1	1	2	1		1	1				
				10. AGGRESSION, IRRITABILITY	1	1	1	1		1	1				
				11. SELF-AGGRESSION	2	1	1	1		1	1				
				12. GLOBAL EVALUATION	2	1	1	1		1	1				
11. Total score	16	12	12	11		9	10								

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55

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PHARMACIA CNS RAD
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
7/02	535	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	1
				02. BODY GESTURES	1	1	1	1	1	1	1	
				03. LOOK	1	1	1	1	1	1	1	
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	
				05. SPEECH	2	2	2	2	2	2	2	
				06. VOICE	1	1	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1	
				09. ANGUISH, ANXIETY	3	3	3	3	3	3	3	
				10. AGGRESSION, IRRITABILITY	2	2	2	2	2	2	2	
				11. SELF-AGGRESSION	2	2	2	2	2	2	2	
12. GLOBAL EVALUATION	2	2	2	2	2	2	2					
11. Total score	18	17	17	18	16	16	13					
536	Reboxetine	Female	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	1	1
			02. BODY GESTURES	1	1	1	1	1	1	1		
			03. LOOK	1	1	1	1	1	1	1		
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1		
			05. SPEECH	2	1	1	1	1	1	1		
			06. VOICE	1	1	1	1	1	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2		
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1		
			09. ANGUISH, ANXIETY	1	1	1	1	1	1	1		
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0		
			11. SELF-AGGRESSION	1	1	1	1	1	1	1		
12. GLOBAL EVALUATION	2	2	2	2	2	2	2					
11. Total score	15	13	11	11	12	12	12					
7/03	167	Imipramine	Female	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	1
				02. BODY GESTURES	1	1	1	1	1	1	1	
				03. LOOK	1	1	1	1	1	1	1	
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0	
				05. SPEECH	1	1	1	1	1	1	1	
				06. VOICE	1	1	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2	
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2	
				09. ANGUISH, ANXIETY	2	2	2	2	2	2	2	
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	
				11. SELF-AGGRESSION	1	1	1	1	1	1	1	
12. GLOBAL EVALUATION	0	0	0	0	0	0	0					
11. Total score	14	13	13	13	13	9	9					
188	188	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	
				02. BODY GESTURES	2	2	2	2	2	2	2	
				03. LOOK	1	1	1	1	1	1	1	
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0	
				05. SPEECH	1	1	1	1	1	1	1	

1451

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56

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	188	Placebo	Male	06.VOICE	1	1	1	1	1	1	1
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	
				09.ANGUISH, ANXIETY	1	1	1	1	1	1	
				10.AGRESSION, IRRITABILITY	2	2	2	1	1	0	
				11.SELF-AGGRESSION	0	0	0	0	0	0	
				12.GLOBAL EVALUATION	2	2	2	1	1	1	
				11.Total score	14	14	14	9	9	7	
				01.FACIAL EXPRESSION	2	2	2	0	0	0	
				02.BODY GESTURES	2	2	2	0	0	0	
				03.LOOK	1	1	1	0	0	0	
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	
05.SPEECH	2	2	2	1	1	1					
06.VOICE	1	1	1	1	1	1					
07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	0	0	0					
08.CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1					
09.ANGUISH, ANXIETY	1	1	1	1	1	1					
10.AGRESSION, IRRITABILITY	1	1	1	1	1	1					
11.SELF-AGGRESSION	0	0	0	0	0	0					
12.GLOBAL EVALUATION	2	2	2	1	1	1					
11.Total score	16	16	16	6	6	6					
190	Reboxetine	Male	01.FACIAL EXPRESSION	4	4	4	1	1	4	4	4
			02.BODY GESTURES	3	3	3	1	3	3		
			03.LOOK	2	2	2	0	2	2		
			04.OUTWARD APPEARANCE	0	0	0	0	0	0		
			05.SPEECH	2	2	2	1	1	1		
			06.VOICE	1	1	1	1	1	1		
			07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	2	2		
			08.CONTACTS, AFFECTIVE NEED	1	1	1	1	2	2		
			09.ANGUISH, ANXIETY	1	1	1	1	1	1		
			10.AGRESSION, IRRITABILITY	0	0	0	0	1	1		
			11.SELF-AGGRESSION	0	0	0	0	1	1		
			12.GLOBAL EVALUATION	1	1	1	1	1	1		
11.Total score	16	16	16	12	19	19					
191	Imipramine	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2	2
			02.BODY GESTURES	2	2	2	2	2	2		
			03.LOOK	1	1	1	1	1	1		
			04.OUTWARD APPEARANCE	0	0	0	0	0	0		
			05.SPEECH	2	2	2	2	2	2		
			06.VOICE	1	1	1	1	2	2		
			07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2		
			08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1		
			09.ANGUISH, ANXIETY	1	1	1	1	1	1		
			10.AGRESSION, IRRITABILITY	1	1	1	1	1	1		
			11.SELF-AGGRESSION	1	1	1	1	1	1		
			12.GLOBAL EVALUATION	3	3	3	3	3	3		

9550082

57

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PHARMACIA CNS 88D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	191	Imigranine	Female	11..Total score	18	18	18	18	19	19	
	192	Reboxetine	Female	01..FACIAL EXPRESSION	2	2	1	2	2	2	2
				02..BODY GESTURES	2	2	1	2	2	2	2
				03..LOOK	0	0	0	0	0	0	0
				04..OUTWARD APPEARANCE	2	2	1	2	2	2	2
				05..SPEECH	3	3	2	2	2	2	2
				06..VOICE	3	3	2	2	2	2	2
				07..ADAPTABILITY, SUGGESTIBILITY	3	3	2	3	3	3	3
				08..CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1
				09..ANGUISH, ANXIETY	1	1	1	1	1	1	1
				10..AGGRESSION, IRRITABILITY	2	2	2	2	2	2	2
				11..SELF-AGGRESSION	1	1	1	1	1	1	1
				12..GLOBAL EVALUATION	2	2	2	2	2	2	2
				11..Total score	22	22	17	20	20	20	20
	523	Reboxetine	Female	01..FACIAL EXPRESSION	3	3	3	1	1	1	1
				02..BODY GESTURES	2	2	2	1	1	1	1
				03..LOOK	1	1	1	0	0	0	0
				04..OUTWARD APPEARANCE	1	1	1	0	0	0	0
				05..SPEECH	2	2	2	2	2	2	2
				06..VOICE	1	1	1	1	1	1	1
				07..ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2
				08..CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1
				09..ANGUISH, ANXIETY	2	2	2	2	2	2	2
				10..AGGRESSION, IRRITABILITY	0	0	1	1	1	1	1
				11..SELF-AGGRESSION	1	1	1	0	0	0	0
				12..GLOBAL EVALUATION	2	2	2	2	2	2	2
				11..Total score	18	18	19	11	12	12	13
	524	Placebo	Female	01..FACIAL EXPRESSION	3	3	2	0	0	0	0
				02..BODY GESTURES	2	2	2	1	1	1	1
				03..LOOK	1	1	1	1	1	1	1
				04..OUTWARD APPEARANCE	1	1	0	0	0	0	0
				05..SPEECH	3	3	3	2	2	2	2
				06..VOICE	1	1	1	1	1	1	1
				07..ADAPTABILITY, SUGGESTIBILITY	2	2	1	2	2	2	2
				08..CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	1
				09..ANGUISH, ANXIETY	2	2	2	1	1	1	1
				10..AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1
				11..SELF-AGGRESSION	1	1	1	1	1	1	1
				12..GLOBAL EVALUATION	3	2	2	2	2	2	2
				11..Total score	23	22	18	13	13	13	13
	525	Placebo	Female	01..FACIAL EXPRESSION	3	3	1	1	0	0	0
				02..BODY GESTURES	3	3	2	2	0	0	0
				03..LOOK	2	2	1	1	0	0	0
				04..OUTWARD APPEARANCE	0	0	0	0	0	0	0

1453

9550082

58

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	525	Placibo	Female	05. SPEECH	2	2	1	1	0	0	0
				06. VOICE	3	3	1	1	0	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	1	1	1
				08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	1
				09. ANGUISH, ANXIETY	3	3	1	1	1	0	0
				10. AGGRESSION, IRRITABILITY	2	2	2	2	1	1	1
				11. SELF-AGGRESSION	1	1	1	1	0	0	0
				12. GLOBAL EVALUATION	2	2	0	0	0	0	0
				11. Total score	25	25	19	13	4	3	3
	526	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	2	3	1	0
				02. BODY GESTURES	3	3	2	2	3	2	0
				03. LOOK	2	2	2	2	2	1	0
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	0
				05. SPEECH	2	2	2	2	2	1	0
				06. VOICE	2	2	2	2	2	2	1
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	1	1
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1
				09. ANGUISH, ANXIETY	3	3	2	3	3	1	1
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1
				11. SELF-AGGRESSION	1	1	1	1	1	1	1
				12. GLOBAL EVALUATION	2	2	2	2	2	2	0
				11. Total score	22	22	19	22	23	13	16
	527	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	1	1	1	1
				02. BODY GESTURES	2	2	2	0	0	0	0
				03. LOOK	1	1	1	1	1	1	1
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05. SPEECH	1	1	1	1	1	1	1
				06. VOICE	1	1	1	1	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	2	2	2	2
				08. CONTACTS, AFFECTIVE NEED	3	3	3	2	2	2	2
				09. ANGUISH, ANXIETY	4	4	4	4	4	4	4
				10. AGGRESSION, IRRITABILITY	2	2	2	1	1	1	1
				11. SELF-AGGRESSION	1	1	1	1	1	1	1
				12. GLOBAL EVALUATION	1	1	1	1	1	1	1
				11. Total score	21	21	21	13	13	13	13
	528	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	2	2	2	2
				02. BODY GESTURES	2	2	2	2	2	2	2
				03. LOOK	1	1	1	1	1	1	1
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05. SPEECH	1	1	1	1	1	1	1
				06. VOICE	1	1	1	1	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2
				08. CONTACTS, AFFECTIVE NEED	3	3	3	3	3	3	3
				09. ANGUISH, ANXIETY	3	3	3	3	3	3	3
				10. AGGRESSION, IRRITABILITY	2	2	2	2	2	2	2
				11. SELF-AGGRESSION	1	1	1	1	1	1	1

9550082

59

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	528	Imipramine	Female	12. GLOBAL EVALUATION 11. Total score	0 18	0 18	0 19	0 19	0 19	0 19	0 19
7/04	193	Placebo	Female	01. FACIAL EXPRESSION 02. BODY GESTURES 03. LOOK 04. OUTWARD APPEARANCE 05. SPEECH 06. VOICE 07. ADAPTABILITY, SUGGESTIBILITY 08. CONTACTS, AFFECTIVE NEED 09. ANGUISH, ANXIETY 10. AGGRESSION, IRRITABILITY 11. SELF-AGGRESSION 12. GLOBAL EVALUATION 11. Total score	3 2 2 2 2 2 2 3 2 1 2 25	2 2 2 2 2 1 2 2 2 1 2 21	2 2 2 1 1 1 2 2 2 1 1 19	1 2 2 1 1 1 1 1 1 1 1 14	1 1 1 2 1 1 1 1 1 1 1 14	0 1 0 0 1 1 0 0 0 0 0 5	
194		Reboxetine	Male	01. FACIAL EXPRESSION 02. BODY GESTURES 03. LOOK 04. OUTWARD APPEARANCE 05. SPEECH 06. VOICE 07. ADAPTABILITY, SUGGESTIBILITY 08. CONTACTS, AFFECTIVE NEED 09. ANGUISH, ANXIETY 10. AGGRESSION, IRRITABILITY 11. SELF-AGGRESSION 12. GLOBAL EVALUATION 11. Total score	3 3 2 2 3 3 2 2 2 1 2 25	3 3 2 1 3 2 2 2 2 2 2 27	1 2 2 1 2 2 2 2 2 1 2 22	2 2 1 1 2 2 1 1 1 1 1 18	1 2 2 1 1 1 1 1 1 1 1 12	1 0 0 0 1 1 0 0 0 0 0 6	
195		Placebo	Female	01. FACIAL EXPRESSION 02. BODY GESTURES 03. LOOK 04. OUTWARD APPEARANCE 05. SPEECH 06. VOICE 07. ADAPTABILITY, SUGGESTIBILITY 08. CONTACTS, AFFECTIVE NEED 09. ANGUISH, ANXIETY 10. AGGRESSION, IRRITABILITY 11. SELF-AGGRESSION 12. GLOBAL EVALUATION 11. Total score	2 3 2 2 2 3 2 2 2 1 1 24	2 3 2 2 2 3 2 2 2 1 1 24	2 3 2 2 2 3 2 2 2 1 1 24	1 1 2 1 1 2 2 2 1 1 1 15	0 0 1 1 1 1 1 1 1 1 1 9	0 0 1 1 0 0 1 1 0 0 0 5	
196		Reboxetine	Female	01. FACIAL EXPRESSION 02. BODY GESTURES 03. LOOK	2 2 2	2 2 2	2 2 2	1 1 2	1 1 1	1 1 1	0 0 0

1455

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60

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
7/04	196	Reboxetine	Female	04. OUTWARD APPEARANCE	2	2	2	2	1	0	0				
				05. SPEECH	2	2	2	2	1	1	1				
				06. VOICE	3	3	3	2	1	1	1				
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	1	1	0				
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	1	0	0				
				09. ANGUISH, ANXIETY	2	2	2	2	1	0	0				
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	0				
				11. SELF-AGGRESSION	2	2	2	2	1	1	0				
				12. GLOBAL EVALUATION	2	2	2	2	1	1	0				
				11. Total score	23	23	23	23	17	12	7	2			
				197	Imipramine	Male	01. FACIAL EXPRESSION	2	2	2	2	2	2	2	2
							02. BODY GESTURES	3	3	3	3	3	2	2	2
03. LOOK	2	2	2				2	2	2	2	2				
04. OUTWARD APPEARANCE	2	2	2				2	2	2	2	2				
05. SPEECH	2	2	2				2	2	2	2	2				
06. VOICE	1	1	1				1	1	1	1	1				
07. ADAPTABILITY, SUGGESTIBILITY	2	2	2				2	2	2	2	2				
08. CONTACTS, AFFECTIVE NEED	2	2	2				2	2	2	2	2				
09. ANGUISH, ANXIETY	2	2	2				2	2	2	2	2				
10. AGGRESSION, IRRITABILITY	1	1	1				1	1	1	1	1				
11. SELF-AGGRESSION	2	2	2				2	2	2	2	2				
12. GLOBAL EVALUATION	23	23	23				22	22	21	21					
198	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1				
			02. BODY GESTURES	2	2	1	1	1	1	1					
			03. LOOK	2	2	1	1	1	1	1					
			04. OUTWARD APPEARANCE	2	2	2	2	2	2	2					
			05. SPEECH	3	3	3	3	3	3	3					
			06. VOICE	2	2	2	2	2	2	2					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2					
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2					
			09. ANGUISH, ANXIETY	2	2	2	2	2	2	2					
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1					
			11. SELF-AGGRESSION	2	2	2	2	2	2	2					
			12. GLOBAL EVALUATION	2	2	2	2	2	2	2					
11. Total score	25	25	18	16	12	14	10								
199	Imipramine	Male	01. FACIAL EXPRESSION	2	2	2	2	2	1	1	0				
			02. BODY GESTURES	3	3	3	3	2	1	1					
			03. LOOK	2	2	2	2	2	2	2					
			04. OUTWARD APPEARANCE	2	2	2	2	2	2	2					
			05. SPEECH	2	2	2	2	2	2	2					
			06. VOICE	1	1	1	1	1	1	1					
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2					
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2					
			09. ANGUISH, ANXIETY	2	2	2	2	2	2	2					
			10. AGGRESSION, IRRITABILITY	2	2	2	2	2	2	2					
			11. SELF-AGGRESSION	2	2	2	2	2	2	2					
			12. GLOBAL EVALUATION	2	2	2	2	2	2	2					

1456

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61

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012a/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
7/04	199	Imipramine	Male	11. SELF-AGGRESSION	2	1	2	1	0	0	0	
				12. GLOBAL EVALUATION	2	2	2	1	1	1	1	
				11. Total score	24	24	25	20	11	9	8	
	200	Placebo	Male	01. FACIAL EXPRESSION	2	2	2	2	2	2	2	2
				02. BODY GESTURES	3	2	2	3	2	2	2	2
				03. LOOK	3	2	2	2	1	1	1	1
				04. OUTWARD APPEARANCE	2	2	2	3	2	2	2	2
				05. SPEECH	2	2	2	2	2	2	2	2
				06. VOICE	2	3	2	2	3	3	3	3
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	3	2	2	2	2	2
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2	2
				09. ANGUISH, ANXIETY	2	2	2	2	2	2	2	2
10. AGGRESSION, IRRITABILITY				2	2	2	2	1	1	1	1	
11. SELF-AGGRESSION				2	2	2	2	2	1	2	1	
12. GLOBAL EVALUATION				2	2	2	2	2	1	1	1	
11. Total score	26	25	25	26	22	22	21					
201	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	2	1	1	1	1	
			02. BODY GESTURES	3	3	3	3	2	2	2		
			03. LOOK	3	3	3	2	2	1	1		
			04. OUTWARD APPEARANCE	2	2	2	1	1	1	1		
			05. SPEECH	2	2	3	1	1	1	1		
			06. VOICE	2	3	2	1	1	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	3	2	2	2	1		
			08. CONTACTS, AFFECTIVE NEED	2	2	3	2	2	2	1		
			09. ANGUISH, ANXIETY	2	2	2	1	1	1	0		
			10. AGGRESSION, IRRITABILITY	2	2	2	1	1	1	1		
			11. SELF-AGGRESSION	2	2	2	2	1	1	0		
			12. GLOBAL EVALUATION	2	2	2	2	1	1	0		
11. Total score	26	27	29	15	15	8	8					
202	Reboxetine	Male	01. FACIAL EXPRESSION	3	3	3	3	3	3	2	2	
			02. BODY GESTURES	3	3	3	3	3	2	2		
			03. LOOK	3	3	3	3	3	2	1		
			04. OUTWARD APPEARANCE	3	3	3	3	3	3	2		
			05. SPEECH	3	3	3	3	3	3	2		
			06. VOICE	3	3	3	3	3	3	2		
			07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	3	2	1		
			08. CONTACTS, AFFECTIVE NEED	3	3	3	3	3	2	1		
			09. ANGUISH, ANXIETY	3	3	3	3	3	2	1		
			10. AGGRESSION, IRRITABILITY	3	3	3	3	3	2	2		
			11. SELF-AGGRESSION	2	2	2	2	2	2	1		
			12. GLOBAL EVALUATION	3	3	3	3	3	2	1		
11. Total score	35	35	35	35	35	26	18					
203	Placebo	Female	01. FACIAL EXPRESSION	3	3	3	3	3	3	2	2	
			02. BODY GESTURES	3	3	3	3	3	2	2		

1457

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62

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/04	203	Placebo	Female	03. LOOK	3	3	3	3	3	3	2
				04. OUTWARD APPEARANCE	3	3	3	3	2	2	2
				05. SPEECH	3	3	3	3	3	3	2
				06. VOICE	3	0	4	0	3	3	2
				07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	2	2	2
				08. CONTACTS, AFFECTIVE NEED	3	3	3	3	2	2	2
				09. ANGUISH, ANXIETY	3	3	3	3	2	2	2
				10. AGGRESSION, IRRITABILITY	2	3	3	2	3	2	2
				11. SELF-AGGRESSION	2	3	3	2	2	2	2
				12. GLOBAL EVALUATION	3	3	3	2	2	2	2
				11.Total score	35	33	37	31	29	27	24
1458	204	Imipramine	Female	01. FACIAL EXPRESSION	3	3	3	3	3	2	2
				02. BODY GESTURES	3	3	3	3	3	3	2
				03. LOOK	3	3	3	3	3	3	2
				04. OUTWARD APPEARANCE	3	3	3	3	3	2	1
				05. SPEECH	3	3	3	3	3	2	2
				06. VOICE	3	0	0	3	2	0	2
				07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	2	3	2
				08. CONTACTS, AFFECTIVE NEED	3	3	3	3	2	2	2
				09. ANGUISH, ANXIETY	3	3	3	3	2	2	2
				10. AGGRESSION, IRRITABILITY	3	3	3	3	2	2	2
				11. SELF-AGGRESSION	3	3	3	2	1	2	1
				12. GLOBAL EVALUATION	3	3	2	2	2	1	2
				11.Total score	36	33	31	31	29	22	22
7/05	205	Placebo	Male	01. FACIAL EXPRESSION	3	3	3	3	3	3	3
				02. BODY GESTURES	3	2	3	3	3	3	3
				03. LOOK	3	3	3	3	3	3	3
				04. OUTWARD APPEARANCE	2	2	2	2	2	2	2
				05. SPEECH	2	2	2	2	2	2	2
				06. VOICE	2	2	2	2	2	2	2
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2
				09. ANGUISH, ANXIETY	2	2	2	2	2	2	2
				10. AGGRESSION, IRRITABILITY	1	2	2	2	2	2	2
				11. SELF-AGGRESSION	2	2	2	2	2	2	2
				12. GLOBAL EVALUATION	2	2	2	2	2	2	2
				11.Total score	27	27	26	29	29	28	28
7/06	206	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	2	2	1	1
				02. BODY GESTURES	2	2	2	2	2	2	2
				03. LOOK	3	2	1	1	1	1	1
				04. OUTWARD APPEARANCE	2	2	2	2	1	1	1
				05. SPEECH	3	2	2	1	1	1	1
				06. VOICE	2	2	2	2	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2
				08. CONTACTS, AFFECTIVE NEED	3	3	2	1	1	1	1
				09. ANGUISH, ANXIETY	2	2	2	2	1	1	1

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64

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
7/05	210	Reboxetine	Male	02. BODY GESTURES	2	2	1	1	1	1	1	1
				03. LOOK	1	1	1	1	1	1	1	
				04. OUTWARD APPEARANCE	1	1	1	0	0	0	0	
				05. SPEECH	3	2	2	1	1	1	1	
				06. VOICE	2	2	2	1	0	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	1	
				09. ANGUISH, ANXIETY	1	1	1	1	0	0	0	
				10. AGGRESSION, IRRITABILITY	0	0	0	1	1	1	1	
				11. SELF-AGGRESSION	1	1	1	0	0	0	0	
				12. GLOBAL EVALUATION	2	2	1	1	0	0	0	
11. Total score	18	17	13	11	7	8	8					
541	Reboxetine	Female	01. FACIAL EXPRESSION	3	2	1	1	1	1	1	1	
			02. BODY GESTURES	2	2	1	1	1	1	1		
			03. LOOK	2	2	2	1	0	0	0		
			04. OUTWARD APPEARANCE	3	2	1	1	1	0	0		
			05. SPEECH	3	2	2	1	0	0	0		
			06. VOICE	3	2	2	1	0	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	3	2	2	1	0	0	0		
			08. CONTACTS, AFFECTIVE NEED	1	3	2	2	1	1	1		
			09. ANGUISH, ANXIETY	2	2	1	0	0	0	0		
			10. AGGRESSION, IRRITABILITY	2	2	1	0	0	0	0		
			11. SELF-AGGRESSION	2	2	1	0	0	0	0		
12. GLOBAL EVALUATION	2	2	1	1	1	1	1					
11. Total score	28	24	16	8	5	4	3					
542	Imipramine	Male	01. FACIAL EXPRESSION	3	3	3	3	3	3	2	2	
			02. BODY GESTURES	2	2	2	2	2	2	2		
			03. LOOK	3	3	2	2	2	2	2		
			04. OUTWARD APPEARANCE	2	2	2	2	2	1	1		
			05. SPEECH	3	3	2	2	2	2	2		
			06. VOICE	2	2	2	2	2	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	2	2	1	1		
			08. CONTACTS, AFFECTIVE NEED	3	3	3	2	2	2	2		
			09. ANGUISH, ANXIETY	3	3	2	2	2	1	1		
			10. AGGRESSION, IRRITABILITY	2	2	2	2	1	1	1		
			11. SELF-AGGRESSION	2	2	2	2	1	1	1		
12. GLOBAL EVALUATION	2	2	2	2	1	1	1					
11. Total score	30	30	27	25	19	17	15					
543	Imipramine	Male	01. FACIAL EXPRESSION	3	3	1	1	1	1	1	1	
			02. BODY GESTURES	2	2	1	1	1	1	1		
			03. LOOK	3	2	2	1	1	1	1		
			04. OUTWARD APPEARANCE	2	2	1	1	1	1	1		
			05. SPEECH	3	3	3	2	1	1	1		
			06. VOICE	3	3	2	2	1	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2		
			08. CONTACTS, AFFECTIVE NEED	3	3	3	2	1	1	1		

1460

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65

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
7/05	543	Imipramine	Male	09. ANGUISH, ANXIETY	3	3	2	2	1	1	1				
				10. AGGRESSION, IRRITABILITY	2	2	1	1	1	1					
				11. SELF-AGGRESSION	1	1	1	1	1	1					
				12. GLOBAL EVALUATION	2	2	2	2	1	1					
				11.Total score	29	28	21	18	14	13					
				544	Placebo	Female	01. FACIAL EXPRESSION	3	3	3	3	3	3	3	3
							02. BODY GESTURES	3	3	3	3	3	3		
							03. LOOK	3	3	3	3	3	3		
							04. OUTWARD APPEARANCE	2	2	2	2	2	2		
							05. SPEECH	3	3	3	3	3	3		
							06. VOICE	3	3	3	3	3	3		
							07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	3	3		
08. CONTACTS, AFFECTIVE NEED	3	3	3				3	3	3						
09. ANGUISH, ANXIETY	3	3	3				3	3	3						
10. AGGRESSION, IRRITABILITY	3	3	3				3	3	3						
11. SELF-AGGRESSION	1	1	1				1	1	1						
12. GLOBAL EVALUATION	3	3	3				3	2	3						
11.Total score	32	32	33	32	31	32									
545	Placebo	Male	01. FACIAL EXPRESSION	3	3	3	3	3	3	3	3				
			02. BODY GESTURES	3	3	3	3	3	3						
			03. LOOK	3	3	3	3	3	3						
			04. OUTWARD APPEARANCE	2	2	2	2	2	2						
			05. SPEECH	3	3	3	3	3	3						
			06. VOICE	2	2	2	2	2	2						
			07. ADAPTABILITY, SUGGESTIBILITY	3	3	3	3	3	3						
			08. CONTACTS, AFFECTIVE NEED	3	3	3	3	3	3						
			09. ANGUISH, ANXIETY	3	3	3	3	3	3						
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1						
			11. SELF-AGGRESSION	1	1	1	1	1	1						
			12. GLOBAL EVALUATION	3	3	3	3	3	3						
11.Total score	30	30	30	30	30	30									
546	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	2	1	1	1	1				
			02. BODY GESTURES	2	2	1	1	1	1						
			03. LOOK	2	2	1	1	1	1						
			04. OUTWARD APPEARANCE	1	1	1	1	1	1						
			05. SPEECH	3	2	2	2	1	1						
			06. VOICE	2	2	2	2	1	1						
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	1	1						
			08. CONTACTS, AFFECTIVE NEED	3	2	2	2	2	2						
			09. ANGUISH, ANXIETY	3	2	2	2	1	1						
			10. AGGRESSION, IRRITABILITY	2	1	1	1	1	1						
			11. SELF-AGGRESSION	1	1	1	1	0	0						
			12. GLOBAL EVALUATION	2	2	2	2	1	1						
11.Total score	25	21	20	17	12	11									

1461

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66

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/07	529	Placebo	Female	01.FACIAL EXPRESSION	3	3	3	2	2	2	2
				02.BODY GESTURES	2	2	2	2	2	2	
				03.LOOK	2	2	2	1	1	1	
				04.OUTWARD APPEARANCE	2	2	2	1	1	1	
				05.SPEECH	2	2	2	1	1	1	
				06.VOICE	2	1	2	2	2	1	
				07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	2	1	1	
				08.CONTACTS, AFFECTIVE NEED	2	2	1	2	1	1	
				09.ANGUISH, ANXIETY	2	2	2	1	1	2	
				10.AGRESSION, IRRITABILITY	2	2	2	1	1	1	
				11.SELF-AGGRESSION	2	2	2	1	1	1	
12.GLOBAL EVALUATION	2	1	1	1	1	1					
11.Total score	25	22	22	17	14	14					
530	530	Imipramine	Female	01.FACIAL EXPRESSION	2	2	2	1			
				02.BODY GESTURES	2	2	2	1			
				03.LOOK	2	2	2	1			
				04.OUTWARD APPEARANCE	1	1	1	1			
				05.SPEECH	2	2	2	2			
				06.VOICE	2	2	2	2			
				07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	2			
				08.CONTACTS, AFFECTIVE NEED	2	2	2	2			
				09.ANGUISH, ANXIETY	2	2	2	2			
				10.AGRESSION, IRRITABILITY	1	1	1	1			
				11.SELF-AGGRESSION	2	1	1	1			
12.GLOBAL EVALUATION	2	1	1	1							
11.Total score	20	19	18								
531	531	Reboxetine	Female	01.FACIAL EXPRESSION	3	2	2	1	1	1	1
				02.BODY GESTURES	2	2	2	2	1	1	
				03.LOOK	2	2	2	1	1	1	
				04.OUTWARD APPEARANCE	2	2	2	1	1	1	
				05.SPEECH	2	2	2	1	1	1	
				06.VOICE	2	2	2	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	2	2	2	2	1	1	
				09.ANGUISH, ANXIETY	2	2	2	2	2	1	
				10.AGRESSION, IRRITABILITY	2	2	2	1	1	1	
				11.SELF-AGGRESSION	1	2	1	1	1	1	
12.GLOBAL EVALUATION	2	1	1	1	1	1					
11.Total score	24	23	18	14	13	12					
532	532	Imipramine	Female	01.FACIAL EXPRESSION	2	2	2	2	2	1	1
				02.BODY GESTURES	2	2	2	2	1	1	
				03.LOOK	1	1	2	1	1	1	
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	
				05.SPEECH	2	2	1	2	1	1	
				06.VOICE	1	1	2	2	2	1	
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	1	

1462

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

67

9550082

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
7/07	532	Imipramine	Female	08.CONTACTS, AFFECTIVE NEED	2	1	2	1	2	1	1				
				09.ANGUIISH, ANXIETY	3	3	2	2	2	2	1				
				10.AGRESSION, IRRITABILITY	2	2	1	1	1	0					
				11.SELF-AGGRESSION	2	1	1	1	1	2					
				12.GLOBAL EVALUATION	1	1	2	2	1	0					
				11.Total score	21	19	20	19	17	14					
				533	Reboxetine	Male	01.FACIAL EXPRESSION	2	2	2	2	2	2	1	1
							02.BODY GESTURES	2	1	1	2	1	1	0	
							03.LOOK	2	2	2	1	2	1	1	
							04.OUTWARD APPEARANCE	1	2	2	1	1	1	0	
							05.SPEECH	1	2	2	2	1	1	1	
							06.VOICE	2	2	2	2	1	1	0	
07.ADAPTABILITY, SUGGESTIBILITY	2	2	2				2	1	0	0					
08.CONTACTS, AFFECTIVE NEED	2	2	2				2	2	0	0					
09.ANGUIISH, ANXIETY	1	2	2				2	2	1	1					
10.AGRESSION, IRRITABILITY	1	2	1				1	1	1	1					
11.SELF-AGGRESSION	1	1	1				2	1	1	0					
12.GLOBAL EVALUATION	1	2	1				1	1	1	3					
11.Total score	19	22	21	20	16	10	7								
1463	534	Placebo	Female	01.FACIAL EXPRESSION	2	2	2	1	2	2	1				
				02.BODY GESTURES	2	2	1	1	1	1	0				
				03.LOOK	1	1	1	1	1	1	0				
				04.OUTWARD APPEARANCE	1	2	1	1	1	1	0				
				05.SPEECH	1	1	1	1	1	1	1				
				06.VOICE	2	1	2	1	1	0	1				
				07.ADAPTABILITY, SUGGESTIBILITY	1	2	1	1	1	1	1				
				08.CONTACTS, AFFECTIVE NEED	2	2	2	1	2	1	1				
				09.ANGUIISH, ANXIETY	2	2	2	1	1	1	1				
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	1	1				
				11.SELF-AGGRESSION	1	1	1	1	1	1	0				
				12.GLOBAL EVALUATION	1	2	1	1	1	1	1				
11.Total score	17	19	16	12	14	11	8								
8	211	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	3								
				02.BODY GESTURES	2	2	3								
				03.LOOK	2	2	2								
				04.OUTWARD APPEARANCE	2	2	2								
				05.SPEECH	2	2	2								
				06.VOICE	1	1	2								
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	2								
				08.CONTACTS, AFFECTIVE NEED	2	2	3								
				09.ANGUIISH, ANXIETY	3	3	3								
				10.AGRESSION, IRRITABILITY	0	0	0								
				11.SELF-AGGRESSION	0	0	0								
				12.GLOBAL EVALUATION	2	2	2								
11.Total score	19	19	24												

9550082

68

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	212	Placebo	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2
				02.BODY GESTURES	2	2	2	2	2	2	
				03.LOOK	2	2	2	2	2	2	
				04.OUTWARD APPEARANCE	2	2	2	2	2	2	
				05.SPEECH	1	1	1	1	1	1	
				06.VOICE	1	1	1	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	
				09.ANGUISH, ANXIETY	3	3	3	2	2	2	
				10.AGRESSION, IRRITABILITY	0	0	0	0	1	1	
				11.SELF-AGGRESSION	0	0	0	0	1	1	
				12.GLOBAL EVALUATION	2	2	2	2	2	2	
11.Total score	18	18	18	17	19	19					
213	213	Imipramine	Male	01.FACIAL EXPRESSION	2						
				02.BODY GESTURES	2						
				03.LOOK	2						
				04.OUTWARD APPEARANCE	2						
				05.SPEECH	2						
				06.VOICE	1						
				07.ADAPTABILITY, SUGGESTIBILITY	2						
				08.CONTACTS, AFFECTIVE NEED	2						
				09.ANGUISH, ANXIETY	1						
				10.AGRESSION, IRRITABILITY	1						
				11.SELF-AGGRESSION	1						
				12.GLOBAL EVALUATION	2						
11.Total score	21										
214	214	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	2	1	1	1	1
				02.BODY GESTURES	1	1	1	1	1	1	
				03.LOOK	2	2	2	1	1	1	
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	
				05.SPEECH	1	1	1	1	1	1	
				06.VOICE	1	1	1	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	
				09.ANGUISH, ANXIETY	1	1	1	1	1	1	
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0	
				11.SELF-AGGRESSION	0	0	0	0	0	0	
				12.GLOBAL EVALUATION	2	2	2	2	1	1	
11.Total score	14	14	14	10	10	9					
215	215	Placebo	Female	01.FACIAL EXPRESSION	2	1	1	0	0	0	0
				02.BODY GESTURES	1	1	0	0	0	0	
				03.LOOK	1	0	1	0	0	0	
				04.OUTWARD APPEARANCE	1	0	1	0	0	0	
				05.SPEECH	1	1	1	0	0	0	

1464

9550082

69

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
8	215	Placebo	Female	06. VOICE	0	0	0	0	0	0	0				
				07. ADAPTABILITY, SUGGESTIBILITY	0	0	1	0	0	0	0				
				08. CONTACTS, AFFECTIVE NEED	0	0	1	0	0	0	0				
				09. ANGUISH, ANXIETY	1	0	0	0	0	0	0				
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0				
				11. SELF-AGGRESSION	0	0	1	0	0	0	0				
				12. GLOBAL EVALUATION	1	0	1	0	0	0	0				
				11. Total score	8	3	8	0	0	0	0				
				216	Imipramine	Male	01. FACIAL EXPRESSION	2	2	2	1	1	1	1	1
							02. BODY GESTURES	1	1	1	1	1	1	1	
							03. LOOK	2	2	2	1	1	1	1	
							04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	
05. SPEECH	2	2	2				1	1	1	1					
06. VOICE	1	1	1				1	1	1	1					
07. ADAPTABILITY, SUGGESTIBILITY	2	2	2				2	2	2	2					
08. CONTACTS, AFFECTIVE NEED	0	0	0				0	0	0	0					
09. ANGUISH, ANXIETY	0	0	0				0	0	0	0					
10. AGGRESSION, IRRITABILITY	0	0	4				0	0	0	0					
11. SELF-AGGRESSION	0	0	0				0	0	0	0					
12. GLOBAL EVALUATION	2	2	2				2	2	2	2					
11. Total score	15	15	19	11	11	11	11								
217	Reboxetine	Female	01. FACIAL EXPRESSION	1	1	1	0	0	0	0	0				
			02. BODY GESTURES	0	0	0	0	0	0	0					
			03. LOOK	1	1	0	0	0	0	0					
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1					
			05. SPEECH	1	1	1	1	1	1	1					
			06. VOICE	0	0	0	0	0	0	0					
			07. ADAPTABILITY, SUGGESTIBILITY	1	0	0	0	0	0	0					
			08. CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0	0					
			09. ANGUISH, ANXIETY	0	0	0	0	0	0	0					
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0					
			11. SELF-AGGRESSION	0	0	0	0	0	0	0					
			12. GLOBAL EVALUATION	1	1	0	0	0	0	0					
11. Total score	6	5	3	2	2	2	2								
218	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	1	1	1	0	1				
			02. BODY GESTURES	1	1	1	1	1	1	0					
			03. LOOK	2	2	2	1	1	1	0					
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	0					
			05. SPEECH	1	1	1	1	1	1	1					
			06. VOICE	1	1	1	1	1	1	1					
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1					
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1					
			09. ANGUISH, ANXIETY	1	1	1	1	1	1	1					
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0					
			11. SELF-AGGRESSION	0	0	0	0	0	0	0					
			12. GLOBAL EVALUATION	2	2	2	2	2	2	1					

1465

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

70

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	218	Reboxetine	Female	11.Total score	13	13	13	11	11	7	8
	219	Placebo	Female	01.FACIAL EXPRESSION	0	0	0	0	0	0	0
				02.BODY GESTURES	0	0	0	0	0	0	0
				03.LOOK	0	0	0	0	0	0	0
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	1
				05.SPEECH	1	1	1	1	1	1	1
				06.VOICE	1	1	1	1	1	1	1
				07.ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1
				09.ANGUISH, ANXIETY	0	0	0	0	0	0	0
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0	0
				11.SELF-AGGRESSION	1	1	1	1	1	1	1
				12.GLOBAL EVALUATION	0	0	0	0	0	0	0
				11.Total score	5	5	5	5	5	5	5
	220	Imipramine	Female	01.FACIAL EXPRESSION	2	2	2	1	1	1	1
				02.BODY GESTURES	1	1	0	0	0	0	0
				03.LOOK	1	1	1	1	1	1	1
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	1
				05.SPEECH	1	1	1	1	1	1	1
				06.VOICE	1	1	1	1	1	1	1
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1
				09.ANGUISH, ANXIETY	1	1	0	0	0	0	0
				10.AGRESSION, IRRITABILITY	1	1	0	0	0	0	0
				11.SELF-AGGRESSION	1	1	1	1	1	1	1
				12.GLOBAL EVALUATION	1	1	1	1	1	1	1
				11.Total score	13	13	10	9	9	9	8
	221	Imipramine	Male	01.FACIAL EXPRESSION	2	2	2	1	1	1	1
				02.BODY GESTURES	2	2	2	1	1	1	0
				03.LOOK	1	1	1	1	1	0	0
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	1
				05.SPEECH	1	1	1	1	1	1	1
				06.VOICE	1	1	1	1	1	1	1
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08.CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2
				09.ANGUISH, ANXIETY	1	1	0	0	0	0	0
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0	0
				11.SELF-AGGRESSION	0	0	1	1	1	1	1
				12.GLOBAL EVALUATION	2	2	2	2	2	2	2
				11.Total score	15	15	14	12	9	8	7
	222	Placebo	Female	01.FACIAL EXPRESSION	0	0	0	0	0	0	0
				02.BODY GESTURES	0	0	0	0	0	0	0
				03.LOOK	0	0	0	0	0	0	0
				04.OUTWARD APPEARANCE	1	0	0	0	0	0	0

1466

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9550082

71

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS 8&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
8	222	Placebo	Female	05. SPEECH	1	0	0	0	0	0	0	0			
				06. VOICE	0	0	0	0	0	0	0	0			
				07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0	0			
				08. CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0	0	0			
				09. ANGUISH, ANXIETY	0	0	0	0	0	0	0	0			
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0	0			
				11. SELF-AGGRESSION	0	0	0	0	0	0	0	0			
				12. GLOBAL EVALUATION	0	0	0	0	0	0	0	0			
				11.Total score	2	0	0	0	0	0	0	0	0		
				223	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1
							02. BODY GESTURES	1	1	1	1	1	1	1	
							03. LOOK	1	1	1	1	1	1		
							04. OUTWARD APPEARANCE	1	1	1	1	1	1		
05. SPEECH	1	1	1				1	1	1						
06. VOICE	1	1	0				0	0	0						
07. ADAPTABILITY, SUGGESTIBILITY	1	1	1				1	1	1						
08. CONTACTS, AFFECTIVE NEED	1	1	1				1	1	1						
09. ANGUISH, ANXIETY	1	1	0				0	0	0						
10. AGGRESSION, IRRITABILITY	1	1	1				1	1	1						
11. SELF-AGGRESSION	1	1	1				1	1	1						
12. GLOBAL EVALUATION	1	1	1				1	1	1						
11.Total score	13	13	10				10	9	8						
224	Placebo	Female	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	1				
			02. BODY GESTURES	1	1	1	1	1	1	0					
			03. LOOK	1	1	1	1	1	1	0					
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1					
			05. SPEECH	1	1	1	1	1	1	1					
			06. VOICE	1	1	1	1	1	1	1					
			07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0					
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	0					
			09. ANGUISH, ANXIETY	0	0	0	0	0	0	0					
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1					
			11. SELF-AGGRESSION	1	1	1	1	1	1	1					
			12. GLOBAL EVALUATION	1	0	0	0	0	0	0					
			11.Total score	9	8	8	7	7	4						
225	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	1				
			02. BODY GESTURES	1	1	1	1	1	1	1					
			03. LOOK	0	1	1	1	1	1	0					
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1					
			05. SPEECH	1	1	1	1	1	1	1					
			06. VOICE	0	0	0	0	0	0	0					
			07. ADAPTABILITY, SUGGESTIBILITY	0	1	1	1	1	1	0					
			08. CONTACTS, AFFECTIVE NEED	0	1	1	1	1	1	1					
			09. ANGUISH, ANXIETY	0	0	0	0	0	0	0					
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1					
			11. SELF-AGGRESSION	1	1	1	1	1	1	1					

1467

9550082

72

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
6	225	Placebo	Male	12. GLOBAL EVALUATION	1	1	1	1	1	1	0	
				11. Total score	7	10	10	10	10	10	6	
	226	Reboxetine	Male	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1
				02. BODY GESTURES	1	1	1	1	1	1	1	
				03. LOOK	1	1	1	1	1	1	1	
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	
				05. SPEECH	2	2	1	1	1	1	1	
				06. VOICE	1	1	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	1	
				09. ANGUISH, ANXIETY	1	1	1	1	1	1	1	
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	
11. SELF-AGGRESSION	1	1	1	1	1	1	1					
12. GLOBAL EVALUATION	2	2	1	1	1	1	1					
11. Total score	16	16	12	12	12	12	12					
1468	227	Reboxetine	Male	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	
				02. BODY GESTURES	1	1	1	1	1	1	1	
	03. LOOK	1	1	1	1	1	1	1				
	04. OUTWARD APPEARANCE	1	1	1	1	1	1	1				
	05. SPEECH	1	1	1	1	1	1	1				
	06. VOICE	1	1	1	1	1	1	1				
	07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1				
	08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1				
	09. ANGUISH, ANXIETY	0	0	0	0	0	0	0				
	10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1				
	11. SELF-AGGRESSION	1	1	1	1	1	1	1				
	12. GLOBAL EVALUATION	2	2	1	1	1	1	1				
11. Total score	13	13	11	11	11	11	10					
228	Imipramine	Male	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1	
			02. BODY GESTURES	1	1	1	1	1	1	1		
	03. LOOK	1	1	1	1	1	1	1				
	04. OUTWARD APPEARANCE	1	1	1	1	1	1	1				
	05. SPEECH	1	1	1	1	1	1	1				
	06. VOICE	1	1	1	1	1	1	1				
	07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1				
	08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1				
	09. ANGUISH, ANXIETY	1	1	1	1	1	1	1				
	10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1				
	11. SELF-AGGRESSION	1	1	1	1	1	1	1				
	12. GLOBAL EVALUATION	1	1	1	1	1	1	1				
11. Total score	13	13	11	11	11	11	10					
229	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1	
			02. BODY GESTURES	1	1	1	1	1	1	1		
			03. LOOK	1	1	1	1	1	1	1		

9550082

73

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
8	229	Imipramine	Female	04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	0			
				05. SPEECH	2	2	1	1	1	1	1	1			
				06. VOICE	1	1	1	1	1	1	1	0			
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	0			
				08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	1	1			
				09. ANGUISH, ANXIETY	1	1	0	0	0	0	0	0			
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1			
				11. SELF-AGGRESSION	1	1	1	1	1	1	1	1			
				12. GLOBAL EVALUATION	2	2	1	1	1	1	1	1			
				11.Total score	16	16	11	11	11	11	11	11	8		
				230	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	2	2	1	1	1	1
							02. BODY GESTURES	2	2	2	2	1	1	1	1
03. LOOK	2	2	2				2	1	1	1	1				
04. OUTWARD APPEARANCE	1	1	1				1	1	1	1	1				
05. SPEECH	2	2	2				2	1	1	1	1				
06. VOICE	1	1	1				1	1	1	1	1				
07. ADAPTABILITY, SUGGESTIBILITY	1	1	1				1	1	1	1	1				
08. CONTACTS, AFFECTIVE NEED	2	2	2				2	2	2	2	2				
09. ANGUISH, ANXIETY	1	1	1				1	1	1	1	1				
10. AGGRESSION, IRRITABILITY	1	1	1				1	1	1	1	1				
11. SELF-AGGRESSION	1	1	1				1	1	1	1	1				
12. GLOBAL EVALUATION	2	2	2				2	2	2	2	2				
11.Total score	18	18	18	14	12	12	12	12							
231	Imipramine	Male	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	1				
			02. BODY GESTURES	1	1	1	1	1	1	1	1				
			03. LOOK	1	1	1	1	1	1	1	1				
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	1				
			05. SPEECH	1	1	1	1	1	1	1	1				
			06. VOICE	1	1	0	0	0	0	0	0				
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1	1				
			08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	1	1				
			09. ANGUISH, ANXIETY	0	0	0	0	0	0	0	0				
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1				
			11. SELF-AGGRESSION	1	1	1	1	1	1	1	1				
			12. GLOBAL EVALUATION	1	1	1	1	1	1	1	1				
11.Total score	11	12	9	8	7	7	7	7							
232	Reboxetine	Male	01. FACIAL EXPRESSION	1	1	1	1	1	1	1	0				
			02. BODY GESTURES	1	1	1	1	1	1	1	0				
			03. LOOK	1	1	1	1	1	1	1	1				
			04. OUTWARD APPEARANCE	1	1	1	1	1	1	1	1				
			05. SPEECH	1	1	1	1	1	1	1	1				
			06. VOICE	1	1	1	1	1	1	1	0				
			07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0	0				
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1	1				
			09. ANGUISH, ANXIETY	0	0	0	0	0	0	0	0				
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0	0				

1469

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74

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
8	232	Reboxetine	Male	11.SELF-AGGRESSION	1	1	1	1	1	1	1	
				12.GLOBAL EVALUATION	1	1	1	1	1	1	1	
				11.Total score	9	9	9	9	9	9		
	233	Placebo	Female	01.FACIAL EXPRESSION	2	1	1	1	1	1	1	0
				02.BODY GESTURES	1	1	1	1	1	1		
				03.LOOK	1	1	1	1	1	1		
				04.OUTWARD APPEARANCE	1	1	1	1	1	1		
				05.SPEECH	1	1	1	1	1	1		
				06.VOICE	1	1	1	1	1	0		
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1		
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	0		
				09.ANGUISH, ANXIETY	1	1	1	1	1	0		
10.AGRESSION, IRRITABILITY				1	1	1	1	1	1			
11.SELF-AGGRESSION	1	1	1	1	1	1						
12.GLOBAL EVALUATION	1	1	1	1	1	1						
11.Total score	13	12	12	12	11	10	5					
1470	234	Placebo	Female	01.FACIAL EXPRESSION	2	2	1	1	1	1	1	
				02.BODY GESTURES	1	1	1	1	1	1		
				03.LOOK	1	1	1	1	1	1		
	235	Placebo	Female	04.OUTWARD APPEARANCE	1	1	1	1	1	1	1	
				05.SPEECH	1	1	1	1	1	1		
				06.VOICE	1	1	1	1	1	0		
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1		
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1		
				09.ANGUISH, ANXIETY	1	0	0	0	0	0		
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0		
				11.SELF-AGGRESSION	1	1	1	1	1	1		
				12.GLOBAL EVALUATION	1	1	1	1	1	1		
11.Total score				12	11	10	10	10	9			
8/A	235	Placebo	Female	01.FACIAL EXPRESSION	2	1	1	0	0	0	0	
				02.BODY GESTURES	2	1	1	1	1	1		
				03.LOOK	2	2	1	0	0	1		
	236	Placebo	Female	04.OUTWARD APPEARANCE	2	2	1	0	0	0	1	
				05.SPEECH	1	2	0	0	0	0		
				06.VOICE	1	2	0	0	0	0		
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1		
				08.CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1		
				09.ANGUISH, ANXIETY	2	1	1	1	1	1		
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	1		
				11.SELF-AGGRESSION	1	1	1	1	1	1		
				12.GLOBAL EVALUATION	3	2	1	1	1	1		
11.Total score				20	17	11	8	7	10	6		
236	Placebo	Female	01.FACIAL EXPRESSION	1	1	0	0	0	0	0		
			02.BODY GESTURES	2	1	0	0	0	0			

9550082

75

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8/A	236	Placebo	Female	03. LOOK	2	1	1	0	0	0	0
				04. OUTWARD APPEARANCE	1	1	0	0	0	0	
				05. SPEECH	1	1	0	0	0	0	
				06. VOICE	1	1	0	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	0	
				08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	0	
				09. ANGUISH, ANXIETY	2	1	1	1	0	1	
				10. AGGRESSION, IRRITABILITY	1	1	0	0	0	0	
				11. SELF-AGGRESSION	2	1	1	1	0	0	
				12. GLOBAL EVALUATION	2	2	1	1	0	0	
				11.Total score	19	14	6	5	1	1	
				01.FACIAL EXPRESSION	2	1	1	0	0	0	
02.BODY GESTURES	2	1	1	0	0	0					
03. LOOK	1	1	1	0	0	0					
04. OUTWARD APPEARANCE	2	2	0	0	0	0					
05. SPEECH	2	1	0	0	0	0					
06. VOICE	1	1	0	0	0	0					
07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	1	1	1					
08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	0					
09. ANGUISH, ANXIETY	2	2	1	1	0	0					
10. AGGRESSION, IRRITABILITY	1	1	1	0	0	0					
11. SELF-AGGRESSION	2	2	2	1	0	0					
12. GLOBAL EVALUATION	3	3	2	1	1	0					
11.Total score	21	18	10	5	3	1					
238	Reboxetine	Female	01.FACIAL EXPRESSION	2	0	0	0	0	0	0	0
			02.BODY GESTURES	1	1	1	0	0	0	0	
			03. LOOK	1	1	1	0	0	0	0	
			04. OUTWARD APPEARANCE	2	1	1	0	0	0	0	
			05. SPEECH	1	1	1	0	0	0	0	
			06. VOICE	1	0	0	0	0	0	0	
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	0	
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	0	0	0	
			09. ANGUISH, ANXIETY	1	1	1	1	0	0	0	
			10. AGGRESSION, IRRITABILITY	1	1	1	0	0	0	0	
			11. SELF-AGGRESSION	2	2	2	1	0	0	0	
			12. GLOBAL EVALUATION	3	3	2	1	1	0		
11.Total score	21	18	10	5	3	1					
239	Imipramine	Female	01.FACIAL EXPRESSION	2	1	1	0	0	0	0	0
			02.BODY GESTURES	2	1	1	0	0	0	0	
			03. LOOK	1	1	1	0	0	0	0	
			04. OUTWARD APPEARANCE	1	1	1	0	0	0	0	
			05. SPEECH	1	1	1	0	0	0	0	
			06. VOICE	1	1	1	0	0	0	0	
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	0	0	0	
			08. CONTACTS, AFFECTIVE NEED	1	1	1	0	0	0	0	
			09. ANGUISH, ANXIETY	1	1	1	0	0	0	0	
			10. AGGRESSION, IRRITABILITY	1	1	0	0	0	0	0	
			11. SELF-AGGRESSION	2	2	1	1	0	0		
			12. GLOBAL EVALUATION	16	10	5	4	1	0		
11.Total score	16	10	5	4	1	0					
239	Imipramine	Female	01.FACIAL EXPRESSION	2	1	1	0	0	0	0	0
			02.BODY GESTURES	2	1	1	0	0	0	0	
			03. LOOK	1	1	1	0	0	0	0	
			04. OUTWARD APPEARANCE	1	1	1	0	0	0	0	
			05. SPEECH	1	1	1	0	0	0	0	
			06. VOICE	1	1	1	0	0	0	0	
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	0	0	0	
			08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	0	1	
			09. ANGUISH, ANXIETY	2	2	2	2	2	1	0	

1471

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76

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
8/A	239	Imipramine	Female	10. AGGRESSION, IRRITABILITY	1	1	1	1	0	0	0	
				11. SELF-AGGRESSION	1	1	1	1	1	0	0	
				12. GLOBAL EVALUATION	3	2	2	2	1	0	0	
					11. Total score	19	15	15	9	6	1	1
	240	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1
				02. BODY GESTURES	3	2	2	2	2	1	1	1
				03. LOOK	2	2	2	1	1	1	1	1
				04. OUTWARD APPEARANCE	2	2	1	1	1	1	1	1
				05. SPEECH	2	2	2	1	1	1	1	1
				06. VOICE	2	2	1	1	1	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	3	2	2	2	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	1	1
09. ANGUISH, ANXIETY				3	1	1	1	1	1	1	1	
10. AGGRESSION, IRRITABILITY				1	1	1	1	1	1	1	1	
11. SELF-AGGRESSION				2	2	1	2	2	1	1	1	
12. GLOBAL EVALUATION				5	3	2	2	2	2	2	2	
				11. Total score	27	24	18	16	14	13	12	
553	Placebo	Female	01. FACIAL EXPRESSION	2	2	1	1	1	1	1	1	
			02. BODY GESTURES	2	1	1	1	1	1	1	1	
			03. LOOK	4	1	1	1	1	1	1	1	
			04. OUTWARD APPEARANCE	2	2	2	2	2	1	1	1	
			05. SPEECH	2	2	2	2	1	1	1	1	
			06. VOICE	2	1	1	1	1	1	1	1	
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	1	2	2	2	2	2	
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1	1	
			09. ANGUISH, ANXIETY	2	1	1	1	1	1	1	1	
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1	
			11. SELF-AGGRESSION	2	1	1	1	1	1	1	1	
			12. GLOBAL EVALUATION	3	2	2	2	2	2	2	2	
				11. Total score	22	17	15	15	14	15	15	
554	Reboxetine	Male	01. FACIAL EXPRESSION	2	1	1	1	1	0	0	0	
			02. BODY GESTURES	2	1	1	1	0	0	0	0	
			03. LOOK	2	2	1	1	1	1	0	0	
			04. OUTWARD APPEARANCE	2	2	1	1	0	0	0	0	
			05. SPEECH	2	1	1	1	0	0	0	0	
			06. VOICE	1	1	1	1	1	0	0	0	
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	1	1	1	
			08. CONTACTS, AFFECTIVE NEED	2	2	1	1	1	1	0	0	
			09. ANGUISH, ANXIETY	1	1	1	1	1	1	0	0	
			10. AGGRESSION, IRRITABILITY	1	1	1	1	0	0	0	0	
			11. SELF-AGGRESSION	2	1	1	1	1	1	1	1	
			12. GLOBAL EVALUATION	3	3	2	2	2	1	1	0	
				11. Total score	22	18	14	10	5	3	1	
555	Reboxetine	Female	01. FACIAL EXPRESSION	2	1	1	1	1	1	1	0	

1472

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77

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8/A	555	Reboxetine	Female	02. BODY GESTURES	2	2	2	1	0	1	1
				03. LOOK	2	2	1	1	1	1	0
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	
				05. SPEECH	1	1	1	1	1	1	
				06. VOICE	2	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	1	
				09. ANGUISH, ANXIETY	2	2	1	1	1	1	
				10. AGGRESSION, IRRITABILITY	1	1	1	1	0	0	
				11. SELF-AGGRESSION	2	1	1	1	0	0	
				12. GLOBAL EVALUATION	3	2	2	2	2	2	
				11. Total score	22	18	15	13	10	10	
9	241	Placebo	Female	01. FACIAL EXPRESSION	2	1	1	1	0	0	0
				02. BODY GESTURES	2	2	1	1	1	1	0
				03. LOOK	1	1	1	1	0	0	
				04. OUTWARD APPEARANCE	2	2	1	1	1	1	
				05. SPEECH	2	1	1	1	0	0	
				06. VOICE	2	1	1	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	0	0	
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	
				09. ANGUISH, ANXIETY	2	2	1	0	1	1	
				10. AGGRESSION, IRRITABILITY	1	1	1	0	0	0	
				11. SELF-AGGRESSION	2	1	1	0	0	0	
				12. GLOBAL EVALUATION	3	3	2	2	1	1	
11. Total score	22	18	14	9	5	4					
9	241	Placebo	Female	01. FACIAL EXPRESSION	1	2	2				
				02. BODY GESTURES	0	3	1				
				03. LOOK	1	1	0				
				04. OUTWARD APPEARANCE	1	2	2				
				05. SPEECH	1	3	2				
				06. VOICE	0	3	0				
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1				
				08. CONTACTS, AFFECTIVE NEED	1	1	2				
				09. ANGUISH, ANXIETY	2	2	4				
				10. AGGRESSION, IRRITABILITY	1	2	2				
				11. SELF-AGGRESSION	1	1	1				
				12. GLOBAL EVALUATION	1	1	2				
11. Total score	11	25	19								
242	Reboxetine	Female	01. FACIAL EXPRESSION	1	1	2	2	2			
			02. BODY GESTURES	2	1	1	1	1			
			03. LOOK	1	1	1	1	1			
			04. OUTWARD APPEARANCE	1	0	1	0				
			05. SPEECH	1	1	2	2				
			06. VOICE	1	0	1	2				
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	2				
			08. CONTACTS, AFFECTIVE NEED	1	0	1	1				

1473

9550082

79

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	246	Placebo	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2
				02.BODY GESTURES	2	2	2	2	2	2	
				03.LOOK	1	1	1	1	1	1	
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	
				05.SPEECH	2	2	2	3	3	3	
				06.VOICE	1	1	1	2	2	2	
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	2	2	2	2	
				08.CONTACTS, AFFECTIVE NEED	2	2	2	3	3	3	
				09.ANGUISH, ANXIETY	4	4	4	4	4	4	
				10.AGRESSION, IRRITABILITY	2	2	2	1	1	1	
				11.SELF-AGGRESSION	1	1	1	1	1	1	
				12.GLOBAL EVALUATION	2	2	2	2	2	2	
11.Total score	21	21	22	25	25	25					
247	247	Placebo	Female	01.FACIAL EXPRESSION	1	2	1	1	1	1	1
				02.BODY GESTURES	2	2	1	1	1	1	
				03.LOOK	1	1	1	1	1	1	
				04.OUTWARD APPEARANCE	1	1	0	1	1	1	
				05.SPEECH	1	1	1	1	1	1	
				06.VOICE	1	1	0	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	0	0	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0	
				09.ANGUISH, ANXIETY	2	2	1	2	2	2	
				10.AGRESSION, IRRITABILITY	1	1	0	1	1	1	
				11.SELF-AGGRESSION	1	0	1	1	1	1	
				12.GLOBAL EVALUATION	0	0	0	0	0	0	
11.Total score	11	12	7	11	11	11					
248	248	Placebo	Male	01.FACIAL EXPRESSION	2	2	2	2	2	2	2
				02.BODY GESTURES	2	2	2	2	2	2	
				03.LOOK	1	1	1	2	2	2	
				04.OUTWARD APPEARANCE	1	1	1	3	3	3	
				05.SPEECH	2	2	2	2	2	2	
				06.VOICE	2	2	2	2	2	2	
				07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	0	0	0	
				08.CONTACTS, AFFECTIVE NEED	1	1	2	3	3	3	
				09.ANGUISH, ANXIETY	0	0	0	0	0	0	
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0	
				11.SELF-AGGRESSION	1	1	1	1	1	1	
				12.GLOBAL EVALUATION	1	1	1	1	1	1	
11.Total score	15	14	11	15	15	15					
249	249	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2
				02.BODY GESTURES	1	1	1	1	1	1	
				03.LOOK	1	1	1	1	1	1	
				04.OUTWARD APPEARANCE	4	4	4	4	4	4	
				05.SPEECH	4	4	4	4	4	4	
				06.VOICE	2	2	2	2	2	2	
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	

1475

9550082

80

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	249	Reboxetine	Female	08. CONTACTS, AFFECTIVE NEED	3						
				09. ANGUISH, ANXIETY	2						
				10. AGGRESSION, IRRITABILITY	1						
				11. SELF-AGGRESSION	1						
				12. GLOBAL EVALUATION	3						
				11. Total score	23						
				01. FACIAL EXPRESSION	2	2	2	2	2	2	2
				02. BODY GESTURES	2	2	2	2	2	2	2
				03. LOOK	1	2	1	1	1	1	1
				04. OUTWARD APPEARANCE	2	2	2	2	2	2	2
				05. SPEECH	3	3	3	3	3	3	3
06. VOICE	2	2	2	2	2	2	2				
07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2				
08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1				
09. ANGUISH, ANXIETY	0	0	0	0	0	0	0				
10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0				
11. SELF-AGGRESSION	0	0	0	0	0	0	0				
12. GLOBAL EVALUATION	1	1	1	1	1	1	1				
11. Total score	16	17	13	14	14	14	14				
250	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	2	2	2	2	2
			02. BODY GESTURES	2	2	2	2	2	2	2	
			03. LOOK	1	2	1	1	1	1	1	
			04. OUTWARD APPEARANCE	2	2	2	2	2	2	2	
			05. SPEECH	3	3	3	3	3	3	3	
			06. VOICE	2	2	2	2	2	2	2	
			07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2	
			08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1	
			09. ANGUISH, ANXIETY	0	0	0	0	0	0	0	
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0	
			11. SELF-AGGRESSION	0	0	0	0	0	0	0	
12. GLOBAL EVALUATION	1	1	1	1	1	1	1				
11. Total score	16	17	13	14	14	14	14				
251	Imipramine	Female	01. FACIAL EXPRESSION	3	1	2	1	2	0	0	0
			02. BODY GESTURES	2	2	2	1	0	0	0	
			03. LOOK	1	1	1	1	0	0	0	
			04. OUTWARD APPEARANCE	2	1	0	0	0	0		
			05. SPEECH	3	2	2	2	0	0		
			06. VOICE	2	1	1	1	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	0	0		
			08. CONTACTS, AFFECTIVE NEED	3	2	1	1	0	0		
			09. ANGUISH, ANXIETY	2	1	1	1	1	1		
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0		
			11. SELF-AGGRESSION	1	1	3	0	0	0		
12. GLOBAL EVALUATION	2	2	1	1	0	0					
11. Total score	23	15	18	1	1	1					
252	Reboxetine	Female	01. FACIAL EXPRESSION	1	0	1	1	1	1	1	1
			02. BODY GESTURES	1	0	0	1	1	1	1	
			03. LOOK	0	0	1	1	1	1		
			04. OUTWARD APPEARANCE	2	2	2	2	2	2		
			05. SPEECH	2	2	2	2	2	2		
			06. VOICE	0	0	0	0	0	0		
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1		
			08. CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0		
			09. ANGUISH, ANXIETY	1	2	2	2	2	2		
			10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0		
			11. SELF-AGGRESSION	0	0	0	0	0	0		
12. GLOBAL EVALUATION	0	0	0	0	0	0					
11. Total score	8	7	13	13	13	15					

1476

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81

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0
RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	253	Reboxetine	Female	01.FACIAL EXPRESSION	2	2					
				02.BODY GESTURES	2	1					
				03.LOOK	1	1					
				04.OUTWARD APPEARANCE	1	1					
				05.SPEECH	1	2					
				06.VOICE	2	1					
				07.ADAPTABILITY, SUGGESTIBILITY	2	2					
				08.CONTACTS, AFFECTIVE NEED	2	3					
				09.ANGUISH, ANXIETY	0	3					
				10.AGRESSION, IRRITABILITY	1	1					
				11.SELF-AGGRESSION	1	1					
				12.GLOBAL EVALUATION	1	2					
	11.Total score	16	20								
	254	Imipramine	Female	01.FACIAL EXPRESSION	2	2	2				
				02.BODY GESTURES	2	2	2				
				03.LOOK	1	1	1				
				04.OUTWARD APPEARANCE	0	1	1				
				05.SPEECH	1	2	2				
				06.VOICE	1	1	1				
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1				
				08.CONTACTS, AFFECTIVE NEED	0	1	1				
				09.ANGUISH, ANXIETY	2	3	3				
				10.AGRESSION, IRRITABILITY	1	2	2				
				11.SELF-AGGRESSION	1	1	1				
				12.GLOBAL EVALUATION	0	1	1				
	11.Total score	12	18	18							
	255	Reboxetine	Female	01.FACIAL EXPRESSION	2	2	2	2	2	2	2
				02.BODY GESTURES	2	2	2	2	2	2	2
				03.LOOK	1	1	1	1	1	1	1
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	1
				05.SPEECH	3	2	2	2	2	2	2
				06.VOICE	1	1	1	1	1	1	1
				07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1
				09.ANGUISH, ANXIETY	1	1	1	1	1	1	1
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	1	1
				11.SELF-AGGRESSION	1	1	1	1	1	1	1
				12.GLOBAL EVALUATION	1	1	1	1	1	1	1
	11.Total score	17	16	20	25	25	25	28			
	256	Imipramine	Female	01.FACIAL EXPRESSION	3	3	1	1	1	1	1
				02.BODY GESTURES	3	3	1	1	1	1	1
				03.LOOK	2	2	1	1	1	1	1
				04.OUTWARD APPEARANCE	2	2	1	1	1	1	1
				05.SPEECH	3	3	1	1	1	1	1

1477

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82

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9	256	Imipramine	Female	06.VOICE	2	2	1	1	1	1	1				
				07.ADAPTABILITY, SUGGESTIBILITY	3	2	1	1	1	1					
				08.CONTACTS, AFFECTIVE NEED	3	3	1	1	2	1					
				09.ANGUISH, ANXIETY	1	1	1	1	1	1					
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	0					
				11.SELF-AGGRESSION	3	2	1	1	1	1					
				12.GLOBAL EVALUATION	2	2	1	1	2	1					
				11.Total score	28	26	12	12	17	12					
				257	Placebo	Male	01.FACIAL EXPRESSION	0	0						
							02.BODY GESTURES	1	1						
							03.LOOK	0	0						
							04.OUTWARD APPEARANCE	0	0						
05.SPEECH	1	1													
06.VOICE	0	0													
07.ADAPTABILITY, SUGGESTIBILITY	1	1													
08.CONTACTS, AFFECTIVE NEED	1	0													
09.ANGUISH, ANXIETY	1	2													
10.AGRESSION, IRRITABILITY	1	1													
11.SELF-AGGRESSION	0	0													
12.GLOBAL EVALUATION	1	0													
11.Total score	7	6													
258	Placebo	Male	01.FACIAL EXPRESSION	1	1	1	1	1	1	1	1				
			02.BODY GESTURES	0	0	0	0	0	0						
			03.LOOK	1	1	1	1	1	1						
			04.OUTWARD APPEARANCE	1	1	1	1	1	1						
			05.SPEECH	1	1	1	1	1	1						
			06.VOICE	0	0	0	0	0	0						
			07.ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0						
			08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1						
			09.ANGUISH, ANXIETY	2	3	3	3	3	3						
			10.AGRESSION, IRRITABILITY	0	0	0	0	0	0						
			11.SELF-AGGRESSION	0	0	0	0	0	0						
			12.GLOBAL EVALUATION	1	1	1	1	1	1						
11.Total score	8	9	10	10	12	12									
319	Placebo	Male	01.FACIAL EXPRESSION	2	2	2	2	2	2	2	2				
			02.BODY GESTURES	1	1	1	1	1	1						
			03.LOOK	2	2	2	2	2	2						
			04.OUTWARD APPEARANCE	0	0	0	0	0	0						
			05.SPEECH	1	1	1	1	1	1						
			06.VOICE	1	1	1	1	1	1						
			07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1						
			08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1						
			09.ANGUISH, ANXIETY	1	1	1	1	1	1						
			10.AGRESSION, IRRITABILITY	1	1	1	1	1	1						
			11.SELF-AGGRESSION	3	1	1	1	1	1						
			12.GLOBAL EVALUATION	2	2	2	2	2	2						

1478

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83

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	319	Placebo	Male	11.Total score	16	14	14	17	18	15	10
				01.FACIAL EXPRESSION	1	3	2	3	1	2	1
				02.BODY GESTURES	1	2	0	1	0	1	0
				03.LOOK	0	1	0	1	0	1	0
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05.SPEECH	1	1	1	2	1	2	2
				06.VOICE	1	1	1	1	0	1	0
				07.ADAPTABILITY, SUGGESTIBILITY	1	2	1	2	0	0	0
				08.CONTACTS, AFFECTIVE NEED	1	1	0	1	1	0	0
				09.ANGUISH, ANXIETY	3	3	1	2	1	3	2
				10.AGRESSION, IRRITABILITY	0	0	0	0	0	0	0
				11.SELF-AGGRESSION	1	1	1	2	1	1	1
				12.GLOBAL EVALUATION	1	2	1	2	1	1	0
				11.Total score	11	17	8	17	6	12	6
				01.FACIAL EXPRESSION	1	2	1	0	0	0	0
				02.BODY GESTURES	0	1	0	0	0	0	0
				03.LOOK	0	0	0	0	0	0	0
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05.SPEECH	1	1	1	1	0	0	0
				06.VOICE	0	1	1	1	0	0	0
				07.ADAPTABILITY, SUGGESTIBILITY	1	2	1	1	0	0	0
				08.CONTACTS, AFFECTIVE NEED	0	1	0	0	0	0	0
				09.ANGUISH, ANXIETY	2	2	1	0	0	0	0
				10.AGRESSION, IRRITABILITY	1	1	0	0	0	0	0
				11.SELF-AGGRESSION	1	1	0	0	0	0	0
				12.GLOBAL EVALUATION	0	1	1	0	0	0	0
				11.Total score	6	12	6	2	0	0	0
				01.FACIAL EXPRESSION	1	0	0	0	0	0	0
				02.BODY GESTURES	0	0	0	0	0	0	0
				03.LOOK	0	0	0	0	0	0	0
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05.SPEECH	0	0	0	0	0	0	0
				06.VOICE	0	0	0	0	0	0	0
				07.ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0
				08.CONTACTS, AFFECTIVE NEED	2	0	0	0	0	0	0
				09.ANGUISH, ANXIETY	1	0	0	0	0	0	0
				10.AGRESSION, IRRITABILITY	1	0	0	0	0	0	0
				11.SELF-AGGRESSION	1	0	0	0	0	0	0
				12.GLOBAL EVALUATION	1	0	0	0	0	0	0
				11.Total score	6	0	0	0	0	0	0
				01.FACIAL EXPRESSION	1	1	1	1	0	1	1
				02.BODY GESTURES	1	0	0	1	1	0	0
				03.LOOK	0	0	0	0	0	0	0
				04.OUTWARD APPEARANCE	1	1	1	1	1	1	1

1479

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84

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PHARMACIA CNS R8D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
11	324	Imipramine	Male	05. SPEECH	1	1	1	1	1	1	1	1		
				06. VOICE	1	1	1	1	1	1	1	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0	0	0	0
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	1	1	1	1
				09. ANGUISH, ANXIETY	1	1	0	1	1	1	1	1	1	1
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1	1	1
				11. SELF-AGGRESSION	1	1	1	1	1	1	1	1	1	1
				12. GLOBAL EVALUATION	1	1	1	1	1	1	1	1	1	1
				11.Total score	10	9	9	9	11	8	9	8	9	8
				01. FACIAL EXPRESSION	1	0	0	0	0	0	0	0	0	0
				02. BODY GESTURES	0	0	0	0	0	0	0	0	0	0
03. LOOK	0	0	0	0	0	0	0	0	0	0				
04. OUTWARD APPEARANCE	2	1	1	1	1	1	1	1	1	1				
05. SPEECH	0	0	0	0	0	0	0	0	0	0				
06. VOICE	1	0	0	0	0	0	0	0	0	0				
07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0	0	0	0				
08. CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0	0	0	0	0				
09. ANGUISH, ANXIETY	0	0	0	0	0	0	0	0	0	0				
10. AGGRESSION, IRRITABILITY	1	0	0	0	0	0	0	0	0	0				
11. SELF-AGGRESSION	1	0	0	0	0	0	0	0	0	0				
12. GLOBAL EVALUATION	1	0	0	0	0	0	0	0	0	0				
11.Total score	7	1	1	1	0	0	1	0	0	0	0			
326	326	Placebo	Male	01. FACIAL EXPRESSION	3	3	3	2	4	4	4	4		
				02. BODY GESTURES	2	2	2	2	3	3	3			
				03. LOOK	1	1	1	1	1	1	1			
				04. OUTWARD APPEARANCE	1	1	1	1	1	1	1			
				05. SPEECH	1	1	1	2	1	1	1			
				06. VOICE	2	2	2	1	2	1	2			
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	1	1			
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	1	1	1			
				09. ANGUISH, ANXIETY	1	1	1	1	1	1	1			
				10. AGGRESSION, IRRITABILITY	2	2	2	2	2	1	1			
				11. SELF-AGGRESSION	1	1	1	2	2	2	2			
12. GLOBAL EVALUATION	2	2	2	2	2	2	2							
11.Total score	20	19	21	19	19	19	19							
327	327	Imipramine	Male	01. FACIAL EXPRESSION	1	0	0	0	0	0	0			
				02. BODY GESTURES	0	0	0	0	0	0	0			
				03. LOOK	1	0	0	0	0	0	0			
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0			
				05. SPEECH	0	0	0	0	0	0	0			
				06. VOICE	1	1	1	1	1	1	1			
				07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0			
				08. CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0	0			
				09. ANGUISH, ANXIETY	0	0	0	0	0	0	0			
				10. AGGRESSION, IRRITABILITY	0	0	0	0	0	0	0			
				11. SELF-AGGRESSION	1	1	1	1	1	1	1			

1480

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85

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PHARMACIA CMS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 14.0

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
11	327	Imipramine	Male	12.GLOBAL EVALUATION	0	0							
				11.Total score	4	2							
				01.FACIAL EXPRESSION	1	0							
				02.BODY GESTURES	1	1							
				03.LOOK	1	0							
				04.OUTWARD APPEARANCE	0	0							
				05.SPEECH	1	0							
				06.VOICE	1	1							
				07.ADAPTABILITY, SUGGESTIBILITY	2	0							
				08.CONTACTS, AFFECTIVE NEED	2	1							
				09.ANGUISH, ANXIETY	2	1							
10.AGRESSION, IRRITABILITY	1	1											
11.SELF-AGGRESSION	2	1											
12.GLOBAL EVALUATION	1	1											
11.Total score	14	7											
1481	329	Placebo	Female	01.FACIAL EXPRESSION	0	0	1	0	0	0	0	0	
				02.BODY GESTURES	1	0	1	0	0	0	0	0	0
				03.LOOK	0	0	0	0	0	0	0	0	0
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	0	0	0
				05.SPEECH	0	0	1	0	0	0	0	0	0
				06.VOICE	1	0	0	0	0	0	0	0	0
				07.ADAPTABILITY, SUGGESTIBILITY	0	0	1	0	0	0	0	0	0
				08.CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0	0	0	0
				09.ANGUISH, ANXIETY	1	1	1	2	1	0	0	1	1
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	0	0	0	0
				11.SELF-AGGRESSION	1	1	1	1	1	0	0	0	0
12.GLOBAL EVALUATION	0	0	0	0	0	0	0	0	0				
11.Total score	5	2	7	4	4	0	0	0	0				
330	Reboxetine	Male	01.FACIAL EXPRESSION	2	2	1	0	0	0	0	0		
			02.BODY GESTURES	1	1	1	1	1	0	0	0		
			03.LOOK	1	1	1	0	0	0	0			
			04.OUTWARD APPEARANCE	0	0	0	0	0	0	0			
			05.SPEECH	2	2	1	0	0	0	0			
			06.VOICE	0	0	0	0	0	0	0			
			07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	0	0	0			
			08.CONTACTS, AFFECTIVE NEED	1	1	0	0	0	0	0			
			09.ANGUISH, ANXIETY	2	2	1	1	1	0	0			
			10.AGRESSION, IRRITABILITY	1	2	2	1	1	0	0			
			11.SELF-AGGRESSION	2	2	2	1	1	0	0			
12.GLOBAL EVALUATION	1	1	1	0	0	0	0						
11.Total score	14	15	11	4	3	0	0						
331	Imipramine	Male	01.FACIAL EXPRESSION	0	0	0	0	0	0	1	1		
			02.BODY GESTURES	0	0	0	0	0	0	0			
			03.LOOK	0	0	0	0	0	0	0			

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86

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	331	Imipramine	Male	04. OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05. SPEECH	1	1	0	0	1	1	0
				06. VOICE	0	0	0	0	0	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0
				08. CONTACTS, AFFECTIVE NEED	1	0	0	0	1	0	0
				09. ANGUISH, ANXIETY	1	1	1	0	1	1	1
				10. AGGRESSION, IRRITABILITY	0	1	1	0	1	1	1
				11. SELF-AGGRESSION	1	1	1	0	1	0	1
				12. GLOBAL EVALUATION	0	0	0	0	0	0	0
				11.Total score	4	4	3	0	4	4	4
	332	Reboxetine	Male	01. FACIAL EXPRESSION	2	1	0	0	0	0	0
				02. BODY GESTURES	1	1	0	0	0	0	0
				03. LOOK	1	0	0	0	0	0	0
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05. SPEECH	0	0	0	0	0	0	0
				06. VOICE	1	1	1	0	0	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	0	0	0	0
				08. CONTACTS, AFFECTIVE NEED	1	1	0	0	0	0	0
				09. ANGUISH, ANXIETY	2	1	1	0	0	0	0
				10. AGGRESSION, IRRITABILITY	2	2	1	0	0	0	0
				11. SELF-AGGRESSION	2	1	1	0	0	0	0
				12. GLOBAL EVALUATION	2	2	1	0	0	0	0
				11.Total score	16	12	5	0	0	0	0
	333	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	0	0	0	0
				02. BODY GESTURES	1	0	0	0	0	0	0
				03. LOOK	0	0	0	0	0	0	0
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05. SPEECH	0	0	0	0	0	0	0
				06. VOICE	1	1	0	0	0	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0
				08. CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0	0
				09. ANGUISH, ANXIETY	1	0	0	0	0	0	0
				10. AGGRESSION, IRRITABILITY	1	1	1	0	1	0	0
				11. SELF-AGGRESSION	1	1	1	0	0	0	0
				12. GLOBAL EVALUATION	1	0	1	0	0	0	0
				11.Total score	7	4	3	0	1	0	0
	334	Reboxetine	Female	01. FACIAL EXPRESSION	1						
				02. BODY GESTURES	1						
				03. LOOK	0						
				04. OUTWARD APPEARANCE	0						
				05. SPEECH	1						
				06. VOICE	1						
				07. ADAPTABILITY, SUGGESTIBILITY	0						
				08. CONTACTS, AFFECTIVE NEED	0						
				09. ANGUISH, ANXIETY	1						
				10. AGGRESSION, IRRITABILITY	2						
				11.Total score	1						

1482

9550082

87

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
11	334	Reboxetine	Female	11.SELF-AGGRESSION	1							
				12.GLOBAL EVALUATION	1							
				11.Total score	10							
	335	Placebo	Male	01.FACIAL EXPRESSION	0	0	0	0	0	0	0	0
				02.BODY GESTURES	1	1	1	1	1	1	1	
				03.LOOK	1	0	0	0	0	0	0	
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	0	
				05.SPEECH	1	0	0	0	0	0	1	
				06.VOICE	0	0	0	0	0	0	0	
				07.ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	0	0	0	
				08.CONTACTS, AFFECTIVE NEED	1	0	0	0	0	0	0	
09.ANGUISH, ANXIETY				1	0	0	0	0	0	0		
10.AGRESSION, IRRITABILITY				1	1	1	1	1	1	1		
11.SELF-AGGRESSION				1	2	1	0	0	0	0		
12.GLOBAL EVALUATION	1	0	0	0	0	0	0					
11.Total score	8	4	4	4	0	0	0	3				
336	Imipramine	Female	01.FACIAL EXPRESSION	3	3	3	3	3	3	3	3	
			02.BODY GESTURES	2	2	2	2	2	2	2		
			03.LOOK	1	1	1	1	1	1	1		
			04.OUTWARD APPEARANCE	0	0	0	0	0	0	0		
			05.SPEECH	2	2	2	2	2	2	2		
			06.VOICE	2	2	2	2	2	2	2		
			07.ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2	2		
			08.CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2	2		
			09.ANGUISH, ANXIETY	3	3	3	3	3	3	3		
			10.AGRESSION, IRRITABILITY	2	2	2	2	2	2	2		
			11.SELF-AGGRESSION	2	2	2	2	2	2	2		
12.GLOBAL EVALUATION	2	2	2	2	2	2	2					
11.Total score	23	24	23	23	23	23	23	23				
337	Reboxetine	Female	01.FACIAL EXPRESSION	0	0	0	1	1	2	1	1	
			02.BODY GESTURES	0	0	0	0	1	1	1		
			03.LOOK	0	0	0	0	0	0	0		
			04.OUTWARD APPEARANCE	0	0	0	0	0	0	0		
			05.SPEECH	0	0	0	0	1	1	1		
			06.VOICE	0	0	1	0	1	1	1		
			07.ADAPTABILITY, SUGGESTIBILITY	0	0	0	0	1	1	1		
			08.CONTACTS, AFFECTIVE NEED	0	0	0	0	1	1	1		
			09.ANGUISH, ANXIETY	1	0	0	0	1	1	1		
			10.AGRESSION, IRRITABILITY	0	0	0	0	1	1	1		
			11.SELF-AGGRESSION	0	0	1	1	1	1	1		
12.GLOBAL EVALUATION	0	0	1	1	1	1	1					
11.Total score	1	2	6	6	12	9	9					
338	Imipramine	Male	01.FACIAL EXPRESSION	2	1	1	1	1	1	1		
			02.BODY GESTURES	1	1	1	1	1	1	1		

1483

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88

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 14.6

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
11	338	Imipramine	Male	03. LOOK	1	1							
				04. OUTWARD APPEARANCE	2	1							
				05. SPEECH	1	0							
				06. VOICE	1	1							
				07. ADAPTABILITY, SUGGESTIBILITY	1	1							
				08. CONTACTS, AFFECTIVE NEED	2	1							
				09. ANGUISH, ANXIETY	1	1							
				10. AGGRESSION, IRRITABILITY	1	1							
				11. SELF-AGGRESSION	2	1							
				12. GLOBAL EVALUATION	2	1							
				11. Total score	17	11							
12	367	Reboxetine	Female	01. FACIAL EXPRESSION	1	1	1	0	0	0	0	0	
				02. BODY GESTURES	1	1	1	1	0	0	0	0	
				03. LOOK	0	0	0	0	0	0	0	0	
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0	0	
				05. SPEECH	3	1	1	0	0	0	0	0	
				06. VOICE	3	2	2	2	0	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	3	1	0	0	0	0	0	0	
				08. CONTACTS, AFFECTIVE NEED	3	2	2	0	0	1	0	0	
				09. ANGUISH, ANXIETY	1	0	1	0	0	0	0	0	
				10. AGGRESSION, IRRITABILITY	0	0	0	1	0	0	0	0	
				11. SELF-AGGRESSION	1	1	0	1	0	0	0	0	
12. GLOBAL EVALUATION	3	1	2	0	0	0	0	0					
11. Total score	19	10	10	4	4	0	0	0	1				
368	368	Placebo	Female	01. FACIAL EXPRESSION	2	1	2	1	1	1	1		
				02. BODY GESTURES	2	1	1	1	1	1	1		
				03. LOOK	2	1	1	1	1	1	0		
				04. OUTWARD APPEARANCE	0	0	1	1	1	1	1		
				05. SPEECH	3	3	2	1	1	1	1		
				06. VOICE	3	3	3	1	1	1	1		
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	1	1	1		
				08. CONTACTS, AFFECTIVE NEED	0	2	1	2	1	1	1		
				09. ANGUISH, ANXIETY	0	1	2	0	0	0	0		
				10. AGGRESSION, IRRITABILITY	1	0	0	0	0	0	0		
				11. SELF-AGGRESSION	1	1	0	0	0	0	0		
12. GLOBAL EVALUATION	1	1	1	1	1	1	1						
11. Total score	19	17	17	9	10	11	9						
369	369	Imipramine	Female	01. FACIAL EXPRESSION	1	0	1	2	1	1	2		
				02. BODY GESTURES	0	0	0	0	0	1	3		
				03. LOOK	1	0	0	0	0	0	0		
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0		
				05. SPEECH	1	0	1	1	1	1	1		
				06. VOICE	1	0	0	0	0	0	0		
				07. ADAPTABILITY, SUGGESTIBILITY	1	0	1	1	1	1	1		
				08. CONTACTS, AFFECTIVE NEED	1	0	1	1	1	1	1		
				09. ANGUISH, ANXIETY	2	1	0	2	1	2	3		

1484

9550082

89

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
12	369	Imipramine	Female	10. AGGRESSION, IRRITABILITY	1	1	1	1	1			
				11. SELF-AGGRESSION	3	0	1	3				
				12. GLOBAL EVALUATION	1	0	1	1				
					11. Total score	13	2	9	18			
	370	Placebo	Male	01. FACIAL EXPRESSION	3	1	3	2				
				02. BODY GESTURES	2	1	2	2				
				03. LOOK	1	1	2	1				
				04. OUTWARD APPEARANCE	1	0	1	1				
				05. SPEECH	3	3	3	2				
				06. VOICE	4	1	3	2				
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	3	2				
				08. CONTACTS, AFFECTIVE NEED	2	2	3	2				
09. ANGUISH, ANXIETY				1	1	3	3					
10. AGGRESSION, IRRITABILITY				1	1	2	1					
11. SELF-AGGRESSION				1	1	1	1					
12. GLOBAL EVALUATION				1	1	2	2					
			11. Total score	23	15	27	23					
371	Imipramine	Female	01. FACIAL EXPRESSION	2	0							
			02. BODY GESTURES	2	1							
			03. LOOK	2	1							
			04. OUTWARD APPEARANCE	1	0							
			05. SPEECH	2	0							
			06. VOICE	2	1							
			07. ADAPTABILITY, SUGGESTIBILITY	2	1							
			08. CONTACTS, AFFECTIVE NEED	2	1							
			09. ANGUISH, ANXIETY	3	1							
			10. AGGRESSION, IRRITABILITY	2	0							
			11. SELF-AGGRESSION	2	1							
			12. GLOBAL EVALUATION	1	1							
			11. Total score	23	8							
372	Reboxetine	Male	01. FACIAL EXPRESSION	3	2	1	1	1	0	0	2	
			02. BODY GESTURES	2	2	1	0	1	2	2		
			03. LOOK	3	2	1	1	1	1	2		
			04. OUTWARD APPEARANCE	1	1	0	0	0	0	0		
			05. SPEECH	3	2	0	0	0	0	0		
			06. VOICE	3	2	0	0	0	0	1		
			07. ADAPTABILITY, SUGGESTIBILITY	3	1	1	0	0	0	1		
			08. CONTACTS, AFFECTIVE NEED	2	2	1	1	0	1	2		
			09. ANGUISH, ANXIETY	3	3	1	1	2	1	2		
			10. AGGRESSION, IRRITABILITY	2	1	1	0	2	2	2		
			11. SELF-AGGRESSION	3	3	0	0	1	0	1		
			12. GLOBAL EVALUATION	2	2	1	0	0	0	0		
			11. Total score	30	22	8	5	8	3	16		
373	Reboxetine	Male	01. FACIAL EXPRESSION	1	0	1	0	0	0	0	0	

9550082

90

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
12	373	Reboxetine	Male	02. BODY GESTURES	1	0	0	0	0	0	0
				03. LOOK	0	0	0	0	0	0	
				04. OUTWARD APPEARANCE	1	0	0	0	0	0	
				05. SPEECH	2	0	1	0	0	1	
				06. VOICE	1	0	0	0	0	0	
				07. ADAPTABILITY, SUGGESTIBILITY	1	0	0	0	0	0	
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	
				09. ANGUISH, ANXIETY	2	0	0	1	1	1	
				10. AGGRESSION, IRRITABILITY	2	0	2	1	2	0	
				11. SELF-AGGRESSION	3	1	0	1	1	0	
				12. GLOBAL EVALUATION	1	0	0	0	0	0	
11.Total score	16	2	5	3	5	2					
374	Placebo	Female	01. FACIAL EXPRESSION	2	1	1	1	2	1	1	1
			02. BODY GESTURES	1	2	1	1	1	1		
			03. LOOK	2	2	0	1	2	2		
			04. OUTWARD APPEARANCE	1	0	0	0	0	0		
			05. SPEECH	2	1	1	0	1	1		
			06. VOICE	2	1	1	0	1	1		
			07. ADAPTABILITY, SUGGESTIBILITY	2	1	0	1	2	2		
			08. CONTACTS, AFFECTIVE NEED	2	2	1	2	2	1		
			09. ANGUISH, ANXIETY	3	3	1	1	3	2		
			10. AGGRESSION, IRRITABILITY	2	2	2	2	2	1		
			11. SELF-AGGRESSION	2	1	0	1	1	1		
12. GLOBAL EVALUATION	2	2	1	0	2	1					
11.Total score	23	17	7	14	16	14					
375	Imipramine	Male	01. FACIAL EXPRESSION	3	2	2	2	3	2	2	2
			02. BODY GESTURES	2	2	1	1	2	2		
			03. LOOK	1	1	1	1	1	1		
			04. OUTWARD APPEARANCE	1	0	0	0	0	0		
			05. SPEECH	2	2	2	2	2	2		
			06. VOICE	2	2	2	2	2	2		
			07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1		
			08. CONTACTS, AFFECTIVE NEED	2	2	2	2	2	2		
			09. ANGUISH, ANXIETY	1	1	1	1	1	1		
			10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1		
			11. SELF-AGGRESSION	3	3	3	3	3	3		
12. GLOBAL EVALUATION	2	2	2	2	2	2					
11.Total score	21	21	21	21	21	21					
13	13	Placebo	Male	01. FACIAL EXPRESSION	1	1	0	1	2	2	3
				02. BODY GESTURES	0	1	1	1	1	2	
				03. LOOK	0	0	0	1	1	2	
				04. OUTWARD APPEARANCE	0	0	0	0	0	1	
				05. SPEECH	1	2	1	1	1	3	
				06. VOICE	0	1	0	0	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	2	
				08. CONTACTS, AFFECTIVE NEED	0	0	0	1	1	3	

1486

9550082

91

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	13	Placebo	Male	09. ANGUISH, ANXIETY	1	2	1	2	1	2	2
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	
				11. SELF-AGGRESSION	2	0	1	1	1	1	
				12. GLOBAL EVALUATION	0	0	0	0	1	2	
				11. Total score	7	9	6	10	11	15	
				01. FACIAL EXPRESSION	2	1	2	2	0	1	
				02. BODY GESTURES	1	1	1	2	1	1	
				03. LOOK	1	1	2	1	0	1	
				04. OUTWARD APPEARANCE	1	0	1	0	0	0	
				05. SPEECH	2	2	3	2	1	1	
				06. VOICE	1	0	1	1	0	1	
14	14	Placebo	Male	07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	0	1	0
				08. CONTACTS, AFFECTIVE NEED	2	2	3	1	0	0	
				09. ANGUISH, ANXIETY	2	1	2	1	0	0	
				10. AGGRESSION, IRRITABILITY	3	1	2	1	0	0	
				11. SELF-AGGRESSION	0	0	1	0	0	1	
				12. GLOBAL EVALUATION	1	0	2	2	1	0	
				11. Total score	18	10	22	15	3	10	
				01. FACIAL EXPRESSION	2	2	1	2	2	2	
				02. BODY GESTURES	2	1	1	1	1	1	
				03. LOOK	2	1	1	0	1	1	
				15	15	Imipramine	Female	04. OUTWARD APPEARANCE	0	1	1
05. SPEECH	2	1	1					1	1	2	
06. VOICE	1	1	1					1	1	1	
07. ADAPTABILITY, SUGGESTIBILITY	1	1	1					0	1	1	
08. CONTACTS, AFFECTIVE NEED	1	1	1					1	1	3	
09. ANGUISH, ANXIETY	0	0	0					1	0	1	
10. AGGRESSION, IRRITABILITY	1	0	0					1	0	2	
11. SELF-AGGRESSION	3	2	1					1	3	1	
12. GLOBAL EVALUATION	1	1	1					0	0	1	
11. Total score	16	12	10					9	13	16	
01. FACIAL EXPRESSION	1	2	1					1	1	0	
16	16	Imipramine	Male	02. BODY GESTURES	1	2	1	1	1	1	2
				03. LOOK	1	1	1	1	1	1	
				04. OUTWARD APPEARANCE	0	1	0	0	0	0	
				05. SPEECH	2	1	1	1	1	1	
				06. VOICE	1	1	1	0	1	1	
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	
				08. CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	
				09. ANGUISH, ANXIETY	1	2	0	0	1	1	
				10. AGGRESSION, IRRITABILITY	0	1	2	1	1	1	
				11. SELF-AGGRESSION	0	2	2	0	2	2	
				12. GLOBAL EVALUATION	1	1	1	1	0	1	
11. Total score	11	16	14	8	10	14					

9550082

92

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	17	Reboxetine	Male	01.FACIAL EXPRESSION	2	2	1	1	2	2	2
				02.BODY GESTURES	1	1	1	1	1	1	
				03.LOOK	2	1	1	2	1	1	
				04.OUTWARD APPEARANCE	0	0	1	0	0	0	
				05.SPEECH	2	1	1	1	1	2	
				06.VOICE	1	1	1	0	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	2	0	1	1	
				08.CONTACTS, AFFECTIVE NEED	2	1	1	1	2	1	
				09.ANGUISH, ANXIETY	2	1	2	1	1	1	
				10.AGRESSION, IRRITABILITY	0	1	1	2	1	0	
				11.SELF-AGGRESSION	2	2	1	1	1	1	
12.GLOBAL EVALUATION	1	1	1	1	1	1					
11.Total score	16	13	14	11	13	12	10				
18	18	Reboxetine	Male	01.FACIAL EXPRESSION	1	1	1	1	1	1	1
				02.BODY GESTURES	1	1	0	0	1	0	
				03.LOOK	2	1	2	1	1	1	
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	
				05.SPEECH	2	2	1	1	1	1	
				06.VOICE	1	1	1	0	1	0	
				07.ADAPTABILITY, SUGGESTIBILITY	0	0	1	0	1	0	
				08.CONTACTS, AFFECTIVE NEED	0	0	1	1	0	1	
				09.ANGUISH, ANXIETY	1	1	0	0	1	0	
				10.AGRESSION, IRRITABILITY	2	2	2	2	2	2	
				11.SELF-AGGRESSION	0	2	1	0	1	0	
12.GLOBAL EVALUATION	0	1	0	0	1	0					
11.Total score	10	12	10	6	11	7	5				
409	409	Reboxetine	Male	01.FACIAL EXPRESSION	2	2	2	2	2	1	1
				02.BODY GESTURES	1	1	1	2	1	1	
				03.LOOK	1	1	1	1	1	2	
				04.OUTWARD APPEARANCE	0	0	0	0	0	0	
				05.SPEECH	1	1	1	2	1	1	
				06.VOICE	1	1	1	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	
				08.CONTACTS, AFFECTIVE NEED	1	1	1	1	1	1	
				09.ANGUISH, ANXIETY	3	2	1	1	1	1	
				10.AGRESSION, IRRITABILITY	1	1	1	1	1	1	
				11.SELF-AGGRESSION	2	2	2	2	2	2	
12.GLOBAL EVALUATION	1	1	1	1	1	1					
11.Total score	15	14	15	13	13	13					
410	410	Placebo	Male	01.FACIAL EXPRESSION	2	2	2	2	2	2	1
				02.BODY GESTURES	2	1	2	2	1	1	
				03.LOOK	1	2	2	2	2	2	
				04.OUTWARD APPEARANCE	1	0	0	0	0	0	
				05.SPEECH	2	2	2	1	2	1	
				06.VOICE	1	1	1	1	1	1	
				07.ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	1	2	

1488

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

93

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
13	410	Placebo	Male	08. CONTACTS, AFFECTIVE NEED	1	2	2	2	1	1	2				
				09. ANGUISH, ANXIETY	1	2	1	2	2	2	1				
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	0				
				11. SELF-AGGRESSION	2	2	2	2	2	2	1				
				12. GLOBAL EVALUATION	1	1	1	1	1	1	1				
				11.Total score	17	17	17	17	15	17	12				
				411	Imipramine	Female	01. FACIAL EXPRESSION	2	2	1	2	2	2	2	2
							02. BODY GESTURES	1	1	1	3	3	1	1	
							03. LOOK	1	1	1	1	2	1	1	
							04. OUTWARD APPEARANCE	0	0	0	1	1	0	0	
							05. SPEECH	2	2	2	2	2	2	1	
							06. VOICE	2	1	1	1	1	1	1	
07. ADAPTABILITY, SUGGESTIBILITY	1	1	1				1	1	1	1					
08. CONTACTS, AFFECTIVE NEED	1	1	1				3	2	2	1					
09. ANGUISH, ANXIETY	2	2	0				2	2	2	2					
10. AGGRESSION, IRRITABILITY	2	1	1				2	2	2	0					
11. SELF-AGGRESSION	1	0	0				2	2	0	1					
12. GLOBAL EVALUATION	2	1	0				2	2	1	1					
11.Total score	18	13	9	23	22	13	12								
14	19	Reboxetine	Female	01. FACIAL EXPRESSION	4	4	1	3	3	3	3				
				02. BODY GESTURES	3	3	2	3	3	3	3				
				03. LOOK	3	4	2	2	4	4	4				
				04. OUTWARD APPEARANCE	3	3	1	1	3	3	3				
				05. SPEECH	4	3	2	2	3	3	3				
				06. VOICE	3	4	2	2	3	3	3				
				07. ADAPTABILITY, SUGGESTIBILITY	3	3	1	2	3	3	3				
				08. CONTACTS, AFFECTIVE NEED	4	3	1	2	3	3	4				
				09. ANGUISH, ANXIETY	1	0	0	1	1	1	1				
				10. AGGRESSION, IRRITABILITY	2	1	0	1	1	1	1				
				11. SELF-AGGRESSION	3	3	2	1	3	2	3				
				12. GLOBAL EVALUATION	36	34	16	22	30	22	30				
11.Total score	36	34	16	22	30	22	30								
423	423	Placebo	Male	01. FACIAL EXPRESSION	1	1	2	2	1	1	1				
				02. BODY GESTURES	1	1	1	1	1	1	0				
				03. LOOK	1	1	1	2	1	1	1				
				04. OUTWARD APPEARANCE	0	0	0	0	0	0	0				
				05. SPEECH	1	2	2	2	2	1	1				
				06. VOICE	0	1	1	1	1	1	1				
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1				
				08. CONTACTS, AFFECTIVE NEED	1	2	1	2	0	0	0				
				09. ANGUISH, ANXIETY	1	1	1	1	1	1	1				
				10. AGGRESSION, IRRITABILITY	1	1	1	2	1	1	1				
				11. SELF-AGGRESSION	1	1	1	1	1	0	0				
				12. GLOBAL EVALUATION	1	1	1	1	1	0	0				
11.Total score	10	13	13	15	15	6	6								

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14	20	Imipramine	Female	01. FACIAL EXPRESSION	2	2	2	1	1	0	0
				02. BODY GESTURES	1	1	3	1	1	0	0
				03. LOOK	0	1	1	1	0	0	0
				04. OUTWARD APPEARANCE	0	1	0	0	0	0	0
				05. SPEECH	2	2	2	1	1	0	0
				06. VOICE	1	2	1	1	1	0	0
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	1	0	0	0
				08. CONTACTS, AFFECTIVE NEED	1	1	1	0	1	0	0
				09. ANGUISH, ANXIETY	3	3	2	1	0	0	1
				10. AGGRESSION, IRRITABILITY	1	1	1	1	0	0	1
				11. SELF-AGGRESSION	2	2	0	1	0	0	1
12. GLOBAL EVALUATION	1	1	1	1	1	0	0				
11.Total score	17	18	15	9	7	0	3				
15	25	Reboxetine	Female	01. FACIAL EXPRESSION	2	3	1	2	2	2	2
				02. BODY GESTURES	1	1	1	1	1	1	2
				03. LOOK	1	2	0	0	0	1	2
				04. OUTWARD APPEARANCE	0	1	0	1	1	1	1
				05. SPEECH	2	2	1	2	2	2	2
				06. VOICE	1	2	1	1	2	2	2
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	1	1
				08. CONTACTS, AFFECTIVE NEED	2	1	1	2	2	2	2
				09. ANGUISH, ANXIETY	3	2	2	2	2	2	2
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1
				11. SELF-AGGRESSION	1	1	1	1	2	2	1
12. GLOBAL EVALUATION	1	1	1	1	1	2	1				
11.Total score	16	18	12	17	17	18	1				
15	25	Reboxetine	Female	01. FACIAL EXPRESSION	1	2	1	2	1	2	1
				02. BODY GESTURES	1	1	2	1	1	1	1
				03. LOOK	1	1	1	1	1	1	1
				04. OUTWARD APPEARANCE	1	1	1	1	1	0	0
				05. SPEECH	2	2	1	2	1	2	1
				06. VOICE	1	1	1	2	1	1	1
				07. ADAPTABILITY, SUGGESTIBILITY	1	2	1	1	1	1	0
				08. CONTACTS, AFFECTIVE NEED	0	2	2	1	1	1	0
				09. ANGUISH, ANXIETY	2	1	2	2	1	1	1
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	0	0
				11. SELF-AGGRESSION	1	2	1	2	2	1	1
12. GLOBAL EVALUATION	0	0	0	1	0	0	0				
11.Total score	12	16	16	17	12	11	7				
15	26	Placebo	Male	01. FACIAL EXPRESSION	1	1	1	1	2	1	0
				02. BODY GESTURES	1	1	1	1	1	1	1
				03. LOOK	2	1	0	0	1	0	0
				04. OUTWARD APPEARANCE	1	1	0	0	1	0	0
				05. SPEECH	2	2	1	0	2	0	1

1490

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
15	26	Placebo	Male	06. VOICE	2	1	1	0	1	0	0				
				07. ADAPTABILITY, SUGGESTIBILITY	2	1	1	0	1	0	0				
				08. CONTACTS, AFFECTIVE NEED	1	1	2	0	2	1					
				09. ANGUISH, ANXIETY	1	1	1	0	1	0					
				10. AGGRESSION, IRRITABILITY	2	1	1	1	2	1					
				11. SELF-AGGRESSION	1	1	1	1	1	1					
				12. GLOBAL EVALUATION	0	0	0	0	0	0					
				11.Total score	16	12	9	4	15	5					
				27	27	Imipramine	Female	01. FACIAL EXPRESSION	2	1	1	0	0	0	0
								02. BODY GESTURES	1	1	1	1	0	0	
								03. LOOK	1	0	0	0	0	0	
								04. OUTWARD APPEARANCE	1	0	0	0	0	0	
05. SPEECH	2	1	1					1	0	0					
06. VOICE	1	1	1					0	0	0					
07. ADAPTABILITY, SUGGESTIBILITY	1	1	0					1	0	0					
08. CONTACTS, AFFECTIVE NEED	3	2	0					0	0	0					
09. ANGUISH, ANXIETY	1	2	1					1	0	0					
10. AGGRESSION, IRRITABILITY	1	1	1					1	1	1					
11. SELF-AGGRESSION	2	2	1					2	1	1					
12. GLOBAL EVALUATION	1	0	0					0	0	0					
11.Total score	17	11	7	7	2	2									
28	28	Reboxetine	Female	01. FACIAL EXPRESSION	2	2	1	1	0	0	0				
				02. BODY GESTURES	1	0	0	0	0	0					
				03. LOOK	1	1	0	0	0	0					
				04. OUTWARD APPEARANCE	1	0	0	0	0	0					
				05. SPEECH	2	2	1	1	1	1					
				06. VOICE	1	1	0	0	0	0					
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	0	0					
				08. CONTACTS, AFFECTIVE NEED	0	0	0	0	0	0					
				09. ANGUISH, ANXIETY	1	1	1	1	1	1					
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1					
				11. SELF-AGGRESSION	1	1	1	1	1	1					
				12. GLOBAL EVALUATION	0	0	0	0	0	0					
11.Total score	12	10	6	5	3	3									
29	29	Placebo	Male	01. FACIAL EXPRESSION	1	1	2	2	0	0	0				
				02. BODY GESTURES	1	1	1	1	1	1					
				03. LOOK	1	1	1	1	1	1					
				04. OUTWARD APPEARANCE	0	0	0	0	0	0					
				05. SPEECH	1	2	2	2	2	2					
				06. VOICE	2	2	1	1	1	1					
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	2	2	2					
				08. CONTACTS, AFFECTIVE NEED	2	2	2	2	1	1					
				09. ANGUISH, ANXIETY	1	1	1	1	2	2					
				10. AGGRESSION, IRRITABILITY	3	0	1	0	3	0					
				11. SELF-AGGRESSION	2	2	2	2	2	2					
				12. GLOBAL EVALUATION	1	0	0	0	0	0					

1491

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96

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	29	Placebo	Male	11..Total score	17	14	15	14			
	30	Imipramine	Female	01..FACIAL EXPRESSION	2	2	1	1	0	1	0
				02..BODY GESTURES	2	1	1	1	1	0	0
				03..LOOK	1	1	1	0	0	0	1
				04..OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05..SPEECH	1	1	1	1	1	1	0
				06..VOICE	1	0	0	0	0	0	0
				07..ADAPTABILITY, SUGGESTIBILITY	1	1	1	1	1	0	0
				08..CONTACTS, AFFECTIVE NEED	1	0	0	0	0	0	1
				09..ANGUISSH, ANXIETY	1	1	1	1	1	0	0
				10..AGGRESSION, IRRITABILITY	1	1	0	0	1	1	0
				11..SELF-AGGRESSION	2	2	1	2	1	1	1
				12..GLOBAL EVALUATION	0	0	0	0	0	0	1
				11..Total score	13	10	7	7	6	4	4
403		Imipramine	Female	01..FACIAL EXPRESSION	2	1	1	1	1	0	0
				02..BODY GESTURES	1	1	1	0	0	0	0
				03..LOOK	1	1	1	0	0	0	0
				04..OUTWARD APPEARANCE	0	0	0	0	0	0	0
				05..SPEECH	2	1	1	1	0	1	1
				06..VOICE	0	0	0	0	0	0	0
				07..ADAPTABILITY, SUGGESTIBILITY	1	0	0	0	0	0	0
				08..CONTACTS, AFFECTIVE NEED	1	1	1	1	0	0	0
				09..ANGUISSH, ANXIETY	1	1	1	0	0	0	0
				10..AGGRESSION, IRRITABILITY	0	2	0	1	1	0	0
				11..SELF-AGGRESSION	2	1	1	1	1	1	1
				12..GLOBAL EVALUATION	1	1	1	0	0	0	0
				11..Total score	12	10	7	5	3	2	2
404		Reboxetine	Female	01..FACIAL EXPRESSION	2	1	1	0	1		
				02..BODY GESTURES	1	1	1	1	1		
				03..LOOK	1	0	1	1	0		
				04..OUTWARD APPEARANCE	1	1	0	0	0		
				05..SPEECH	1	2	1	1	1		
				06..VOICE	1	1	1	1	1		
				07..ADAPTABILITY, SUGGESTIBILITY	1	1	0	0	1		
				08..CONTACTS, AFFECTIVE NEED	1	1	1	1	1		
				09..ANGUISSH, ANXIETY	1	1	1	0	0		
				10..AGGRESSION, IRRITABILITY	1	1	1	1	1		
				11..SELF-AGGRESSION	2	2	1	1	1		
				12..GLOBAL EVALUATION	1	1	1	1	1		
				11..Total score	14	13	11	8	8		
405		Placebo	Female	01..FACIAL EXPRESSION	2	1	1	0	0	0	0
				02..BODY GESTURES	2	1	0	0	0	0	0
				03..LOOK	1	0	0	0	0	0	0
				04..OUTWARD APPEARANCE	0	0	0	0	0	0	0

1492

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97

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
15	405	Placebo	Female	05. SPEECH	1	1	1	0	0	0	0	0				
				06. VOICE	0	0	0	0	0	0	0	0				
				07. ADAPTABILITY, SUGGESTIBILITY	1	0	1	0	0	0	0	0				
				08. CONTACTS, AFFECTIVE NEED	1	1	1	0	0	0	0	0				
				09. ANGUISH, ANXIETY	2	1	1	0	0	0	0	0				
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1				
				11. SELF-AGGRESSION	0	0	1	1	1	1	1	1				
				12. GLOBAL EVALUATION	1	0	1	0	0	0	0	0				
				11. Total score	12	6	8	2	2	2	2	2				
				406	406	Imipramine	Male	01. FACIAL EXPRESSION	1	1	1	0	0	0	0	1
								02. BODY GESTURES	1	1	1	0	0	0	0	0
								03. LOOK	1	1	0	0	0	0	0	0
04. OUTWARD APPEARANCE	1	0	0					0	0	0	0	0				
05. SPEECH	1	1	1					1	1	1	1	1				
06. VOICE	1	1	1					1	1	1	1	1				
07. ADAPTABILITY, SUGGESTIBILITY	1	0	0					0	0	0	0	0				
08. CONTACTS, AFFECTIVE NEED	1	1	1					1	1	1	1	1				
09. ANGUISH, ANXIETY	0	0	0					0	0	0	0	0				
10. AGGRESSION, IRRITABILITY	1	1	1					1	1	1	1	1				
11. SELF-AGGRESSION	1	1	1					1	1	1	1	1				
12. GLOBAL EVALUATION	1	0	1					1	1	0	1	1				
11. Total score	11	8	7	5	5	4	4	7								
407	407	Reboxetine	Female	01. FACIAL EXPRESSION	1	1	2	1	1	0	0	0				
				02. BODY GESTURES	2	2	1	1	0	0	0	0				
				03. LOOK	2	1	2	0	0	0	0	0				
				04. OUTWARD APPEARANCE	1	1	1	0	0	0	0	0				
				05. SPEECH	2	1	1	1	1	1	1	1				
				06. VOICE	1	1	1	0	0	0	0	0				
				07. ADAPTABILITY, SUGGESTIBILITY	1	1	2	0	0	0	0	0				
				08. CONTACTS, AFFECTIVE NEED	2	2	1	0	0	1	1	1				
				09. ANGUISH, ANXIETY	1	1	1	0	0	0	0	0				
				10. AGGRESSION, IRRITABILITY	1	1	1	1	1	1	1	1				
				11. SELF-AGGRESSION	1	1	1	1	1	1	1	1				
				12. GLOBAL EVALUATION	1	1	1	0	1	1	1	1				
11. Total score	16	14	15	5	6	5	6	6								
408	408	Placebo	Female	01. FACIAL EXPRESSION	2	2	2	1	1	1	0					
				02. BODY GESTURES	2	2	1	1	0	0	0					
				03. LOOK	1	1	1	1	0	0	0					
				04. OUTWARD APPEARANCE	1	1	0	0	0	0	0					
				05. SPEECH	3	2	2	1	1	1	1					
				06. VOICE	2	2	2	0	1	1	1					
				07. ADAPTABILITY, SUGGESTIBILITY	2	2	2	1	0	0	1					
				08. CONTACTS, AFFECTIVE NEED	2	2	2	1	1	0	1					
				09. ANGUISH, ANXIETY	1	1	1	0	0	0	1					
				10. AGGRESSION, IRRITABILITY	1	0	0	0	0	0	1					
				11. SELF-AGGRESSION	1	1	1	1	1	1	1					
				11. Total score	1	1	1	1	1	1	0					

1493

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98

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 14.0

RELATIONAL DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Relational Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	408	Placebo	Female	12.GLOBAL EVALUATION 11.Total score	2 19	2 18	2 18	0 7	0 6	0 7	1 7
	418	Placebo	Female	01.FACIAL EXPRESSION 02.BODY GESTURES 03.LOOK 04.OUTWARD APPEARANCE 05.SPEECH 06.VOICE 07.ADAPTABILITY, SUGGESTIBILITY 08.CONTACTS, AFFECTIVE NEED 09.ANGUISH, ANXIETY 10.AGRESSION, IRRITABILITY 11.SELF-AGGRESSION 12.GLOBAL EVALUATION 11.Total score	2 1 1 0 2 3 1 0 1 0 1 0 12	2 1 1 0 1 2 1 1 1 1 1 1 15	1 1 0 1 1 0 1 1 1 2 0 8	0 0 0 1 1 0 1 1 1 1 1 1 7	0 0 0 0 0 0 1 1 1 1 1 1 6	0 0 0 0 1 0 0 0 0 1 1 4	
	419	Placebo	Female	01.FACIAL EXPRESSION 02.BODY GESTURES 03.LOOK 04.OUTWARD APPEARANCE 05.SPEECH 06.VOICE 07.ADAPTABILITY, SUGGESTIBILITY 08.CONTACTS, AFFECTIVE NEED 09.ANGUISH, ANXIETY 10.AGRESSION, IRRITABILITY 11.SELF-AGGRESSION 12.GLOBAL EVALUATION 11.Total score	1 1 1 2 0 1 1 1 2 1 1 13	0 1 0 1 0 0 1 1 1 1 1 6	1 0 0 2 0 1 1 1 2 1 1 11	1 0 1 2 1 1 1 1 2 1 1 12	0 0 0 1 0 0 1 1 1 1 1 7	1 0 0 1 1 1 0 1 2 1 1 8	

1494

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1

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	Imipramine	Female	Severity of illness	6.00	6.00	4.00	4.00	3.00	3.00	1.00
				Global improvement		6.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index	14.00	10.00	11.00	6.00	6.00	2.00	
	2	Reboxetine	Male	Efficacy index (*)	0.50	1.00	0.67	1.50	1.50	2.00	
				Severity of illness	6.00	5.00	4.00	4.00	5.00	4.00	
				Global improvement		4.00	3.00	3.00	3.00	3.00	
	3	Imipramine	Male	Efficacy index	13.00	10.00	10.00	10.00	10.00	6.00	
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.50	
				Severity of illness	4.00	3.00	4.00	4.00	3.00	2.00	
	4	Placebo	Male	Global improvement		4.00	4.00	3.00	3.00	2.00	
				Efficacy index	14.00	14.00	10.00	11.00	3.00	6.00	
				Efficacy index (*)	0.50	0.50	1.00	0.67	1.33	1.50	
	5	Reboxetine	Female	Severity of illness	5.00	4.00	2.00	2.00	1.00	1.00	
				Global improvement		2.00	2.00	2.00	1.00	1.00	
				Efficacy index	6.00	6.00	6.00	1.00	1.00	4.00	
	6	Placebo	Female	Efficacy index (*)	1.50	1.50	1.50	1.50	4.00	4.00	
				Severity of illness	5.00	4.00	4.00	4.00	4.00	4.00	
				Global improvement		3.00	3.00	5.00	5.00	3.00	
	7	Reboxetine	Female	Efficacy index	10.00	10.00	10.00	13.00	10.00	1.00	
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	0.25	
				Severity of illness	6.00	4.00	4.00	4.00	4.00	4.00	
	8	Placebo	Male	Global improvement		3.00	3.00	3.00	3.00	3.00	
				Efficacy index	10.00	10.00	10.00	14.00	10.00	16.00	
				Efficacy index (*)	1.00	1.00	1.00	0.50	1.00	2.00	
	9	Reboxetine	Female	Severity of illness	6.00	4.00	4.00	3.00	2.00	1.00	
				Global improvement		3.00	3.00	2.00	1.00	1.00	
				Efficacy index	10.00	10.00	6.00	2.00	2.00	4.00	
	10	Placebo	Male	Efficacy index (*)	2.00	2.00	2.00	1.50	2.00	2.00	
				Severity of illness	4.00	4.00	4.00	3.00	2.00	1.00	
				Global improvement		3.00	2.00	2.00	2.00	2.00	
	11	Reboxetine	Female	Efficacy index	9.00	9.00	9.00	6.00	1.00	1.00	
				Efficacy index (*)	2.00	2.00	2.00	1.50	4.00	4.00	
				Severity of illness	4.00	4.00	4.00	3.00	3.00	1.00	

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1405

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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2

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	9	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	7.00 3.00 10.00 1.00	6.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	5.00 4.00 14.00 0.50	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	3.00 2.00 6.00 1.50
	10	Placebo	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 13.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00
	11	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00 4.00 13.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00
	12	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	3.00 2.00 10.00 1.00	3.00 2.00 10.00 1.00	2.00 1.00 10.00 1.00	2.00 1.00 10.00 1.00	1.00 1.00 10.00 1.00
	412	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00 3.00 14.00 2.00	4.00 3.00 14.00 2.00	5.00 4.00 14.00 0.50	4.00 3.00 10.00 1.00	4.00 2.00 6.00 1.50	3.00 2.00 6.00 1.00	1.00 1.00 4.00 4.00
	413	Placebo	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00 4.00 13.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	3.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	3.00 3.00 10.00 1.00
	414	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	-5.00 4.00 13.00 1.00	4.00 4.00 13.00 1.00	5.00 4.00 9.00 2.00	5.00 4.00 9.00 2.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00
	415	Imipramine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00 4.00 14.00 0.50	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	3.00 2.00 10.00 1.00	3.00 2.00 10.00 1.00	2.00 2.00 10.00 1.00	1.00 1.00 2.00 2.00

1496

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SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=slightly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=initially improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/015

Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	416	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	3.00	2.00	3.00	2.00
				Global improvement	4.00	3.00	3.00	2.00	2.00	2.00	
				Efficacy index	14.00	13.00	13.00	2.00	2.00	2.00	
				Efficacy index (*)	0.50	1.00					
421	421	Imipramine	Male	Severity of illness	4.00	4.00	4.00	3.00	2.00	3.00	2.00
				Global improvement	3.00	3.00	3.00	2.00	2.00	2.00	
				Efficacy index	10.00	11.00	6.00	6.00	2.00	2.00	
				Efficacy index (*)	1.00	0.67	1.50	2.00	2.00	2.00	
422	422	Imipramine	Male	Severity of illness	4.00	4.00	3.00	3.00	3.00	1.00	1.00
				Global improvement	4.00	4.00	2.00	2.00	2.00	2.00	
				Efficacy index	13.00	6.00	6.00	2.00	2.00	2.00	
				Efficacy index (*)	1.00	1.50	1.50	2.00	2.00	2.00	
2/1	49	Placebo	Female	Severity of illness	6.00	5.00	2.00	1.00	1.00	1.00	1.00
				Global improvement	3.00	2.00	2.00	1.00	1.00	1.00	
				Efficacy index	11.00	6.00	2.00	2.00	2.00	2.00	
				Efficacy index (*)	0.67	1.50	2.00	2.00	2.00	2.00	
50	50	Reboxetine	Female	Severity of illness	4.00	3.00	2.00	2.00	2.00	2.00	2.00
				Global improvement	2.00	1.00	1.00	1.00	1.00	1.00	
				Efficacy index	6.00	3.00	3.00	2.00	2.00	3.00	
				Efficacy index (*)	1.50	1.33	1.33	2.00	2.00	1.33	
51	51	Imipramine	Female	Severity of illness	6.00	5.00	4.00	2.00	2.00	2.00	2.00
				Global improvement	3.00	3.00	2.00	1.00	2.00	2.00	
				Efficacy index	10.00	7.00	3.00	3.00	2.00	2.00	
				Efficacy index (*)	1.00	1.00	1.33	2.00	2.00	2.00	
2/2	43	Imipramine	Female	Severity of illness	5.00	4.00	4.00		4.00	2.00	
				Global improvement	3.00	2.00	2.00		4.00	3.00	
				Efficacy index	10.00	5.00	5.00		14.00	10.00	
				Efficacy index (*)	1.00	3.00	3.00	0.50	1.00		
44	44	Imipramine	Female	Severity of illness	5.00	5.00	3.00	3.00	2.00	4.00	3.00
				Global improvement	5.00	3.00	3.00	3.00	2.00	3.00	
				Efficacy index	15.00	6.00	6.00	6.00	6.00	6.00	
				Efficacy index (*)	0.33	1.50	1.50	1.50	1.50	1.50	

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SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
 GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
 EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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4

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/2	45	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	4.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	3.00
				Efficacy index		10.00	6.00	6.00	6.00	2.00	6.00
				Efficacy index (*)		1.00	1.50	1.50	1.50	2.00	1.50
46	46	Placebo	Female	Severity of illness	6.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		10.00	6.00	6.00	1.00	1.00	4.00
				Efficacy index (*)		1.00	1.50	4.00			
47	47	Placebo	Female	Severity of illness	4.00	5.00	3.00	3.00	3.00	4.00	4.00
				Global improvement		3.00	3.00	2.00	3.00	3.00	3.00
				Efficacy index		9.00	5.00	5.00	9.00	9.00	9.00
				Efficacy index (*)		2.00	3.00	2.00	2.00	2.00	
48	48	Reboxetine	Female	Severity of illness	6.00	5.00	5.00	4.00	4.00	2.00	3.00
				Global improvement		3.00	3.00	2.00	2.00	1.00	2.00
				Efficacy index		10.00	4.00	6.00	6.00	2.00	2.00
				Efficacy index (*)		1.00	1.00	1.50	1.50	2.00	2.00
2/3	36/A	Imipramine	Male	Severity of illness	5.00	5.00	4.00	2.00	2.00	1.00	1.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		9.00	1.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		2.00	4.00	2.00	2.00	2.00	2.00
37	37	Reboxetine	Female	Severity of illness	5.00	6.00	6.00	4.00	3.00	3.00	3.00
				Global improvement		5.00	4.00	3.00	2.00	2.00	2.00
				Efficacy index		13.00	13.00	5.00	1.00	1.00	1.00
				Efficacy index (*)		1.00	1.00	3.00	4.00	4.00	4.00
38	38	Placebo	Male	Severity of illness	5.00	3.00	3.00	4.00	3.00	3.00	3.00
				Global improvement		2.00	2.00	3.00	2.00	2.00	2.00
				Efficacy index		5.00	5.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		3.00	3.00	3.00	4.00	4.00	4.00
39	39	Imipramine	Female	Severity of illness	5.00	4.00	4.00	3.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		5.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	3.00	4.00	4.00	4.00	4.00

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1498

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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5

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/3	40	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00	1.00	1.00
				Global improvement		3.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index		6.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		1.50	2.00	4.00	4.00	4.00	4.00
41	Placebo	Male	Severity of illness	6.00	5.00	5.00	5.00	5.00	5.00	4.00	4.00
			Global improvement		4.00	3.00	3.00	3.00	3.00	3.00	
			Efficacy index		14.00	9.00	9.00	10.00	10.00	9.00	
				Efficacy index (*)		0.50	2.00	2.00	1.00	1.00	2.00
42	Imipramine	Female	Severity of illness	5.00	4.00	5.00	5.00	3.00	4.00	4.00	4.00
			Global improvement		3.00	3.00	2.00	2.00	2.00	2.00	
			Efficacy index		5.00	6.00	2.00	2.00	2.00	2.00	
				Efficacy index (*)		3.00	1.50	2.00	2.00	2.00	
2/4	31	Placebo	Male	Severity of illness	5.00	5.00	5.00	5.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	3.00
				Efficacy index		9.00	9.00	9.00	9.00	9.00	9.00
				Efficacy index (*)		2.00	2.00	2.00	2.00	2.00	
32	Reboxetine	Male	Severity of illness	6.00	6.00	6.00	6.00	6.00	5.00	4.00	3.00
			Global improvement		4.00	4.00	5.00	5.00	3.00	3.00	
			Efficacy index		13.00	13.00	13.00	13.00	9.00	9.00	
				Efficacy index (*)		1.00	1.00	1.00	2.00	2.00	3.00
33	Imipramine	Male	Severity of illness	5.00	5.00	5.00	4.00	4.00	4.00	3.00	1.00
			Global improvement		4.00	4.00	3.00	3.00	2.00	2.00	
			Efficacy index		9.00	9.00	5.00	5.00	1.00	1.00	
				Efficacy index (*)		2.00	2.00	3.00	3.00	4.00	4.00
34	Placebo	Female	Severity of illness	6.00	6.00	6.00	6.00	5.00	4.00	2.00	2.00
			Global improvement		4.00	4.00	3.00	2.00	2.00	1.00	
			Efficacy index		13.00	13.00	9.00	5.00	1.00	1.00	
				Efficacy index (*)		1.00	1.00	2.00	3.00	4.00	4.00
35	Reboxetine	Female	Severity of illness	6.00	6.00	6.00	4.00	4.00	3.00	3.00	2.00
			Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	
			Efficacy index		9.00	9.00	5.00	5.00	1.00	1.00	
				Efficacy index (*)		2.00	2.00	3.00	3.00	3.00	4.00

1499

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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6

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/4	36	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 4.00 13.00 1.00	6.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00	4.00 4.00 13.00 1.00	3.00 3.00 9.00 2.00	2.00 2.00 5.00 3.00	2.00 2.00 5.00 3.00
2/5	73	Placebo	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00 3.00 10.00 1.00	3.00 3.00 9.00 2.00	3.00 3.00 9.00 2.00	4.00 4.00 9.00 2.00	4.00 3.00 9.00 2.00	5.00 5.00 13.00 1.00	5.00 6.00 13.00 1.00
74		Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 3.00 10.00 1.00	4.00 3.00 6.00 1.50	3.00 3.00 6.00 1.50	2.00 2.00 6.00 1.50	2.00 2.00 5.00 3.00	2.00 2.00 1.60 4.00	1.00 1.00 1.60 4.00
75		Imipramine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 3.00 9.00 2.00	5.00 2.00 5.00 3.00	4.00 2.00 5.00 3.00	3.00 2.00 1.00 4.00	1.00 1.00 1.00 4.00	2.00 1.00 1.00 4.00	1.00 1.00 1.00 4.00
76		Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 3.00 11.00 0.67	6.00 3.00 11.00 0.67	4.00 2.00 2.00 2.00	6.00 6.00 13.00 1.00	3.00 2.00 6.00 1.59	2.00 2.00 2.00 2.00	2.00 1.00 2.00 2.00
77		Placebo	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 3.00 5.00 3.00	4.00 2.00 5.00 3.00	4.00 2.00 5.00 3.00	3.00 2.00 1.00 4.00	2.00 2.00 1.00 4.00	2.00 1.00 1.00 4.00	2.00 1.00 1.00 4.00
78		Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 3.00 9.00 2.00	6.00 3.00 9.00 2.00	3.00 2.00 9.00 2.00	3.00 2.00 5.00 3.00	2.00 2.00 2.00 2.00	2.00 1.00 2.00 2.00	2.00 1.00 2.00 2.00
2/6	55	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 4.00 13.00 1.00	6.00 4.00 9.00 1.00	5.00 3.00 9.00 2.00	2.00 2.00 5.00 3.00	2.00 1.00 5.00 4.00	1.00 1.00 1.00 4.00	1.00 1.00 1.00 4.00

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SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=moderately ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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7

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2/6	56	Reboxetine	Female	Severity of illness	6.00	6.00	6.00	6.00	4.00	4.00	5.00
				Global improvement		4.00	4.00	4.00	2.00	2.00	3.00
				Efficacy index		13.00	13.00	13.00	5.00	5.00	9.00
				Efficacy index (*)		1.00	1.00	1.00	3.00	3.00	2.00
	57	Imipramine	Female	Severity of illness	5.00	5.00	3.00	1.00	1.00	1.00	1.00
				Global improvement		4.00	3.00	1.00	1.00	1.00	1.00
				Efficacy index		13.00	10.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.00	2.00	2.00	2.00	2.00
	58	Placebo	Female	Severity of illness	6.00	6.00	6.00	2.00	1.00	1.00	1.00
				Global improvement		4.00	4.00	2.00	1.00	1.00	1.00
				Efficacy index		13.00	13.00	2.00	2.00	2.00	1.00
				Efficacy index (*)		1.00	1.00	2.00	2.00	2.00	4.00
	59	Placebo	Male	Severity of illness	6.00	6.00	6.00	6.00	6.00	6.00	6.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.00
	60	Imipramine	Female	Severity of illness	6.00	6.00	2.00	1.00	1.00	1.00	1.00
				Global improvement		4.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		13.00	6.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.50	2.00	2.00	2.00	2.00
3/1	61	Imipramine	Male	Severity of illness	4.00	4.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		5.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		14.00	10.00	6.00	6.00	6.00	5.00
				Efficacy index (*)		0.50	1.00	1.50	1.50	3.00	3.00
	62	Imipramine	Female	Severity of illness	6.00	6.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		5.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	3.00	4.00	4.00	4.00	4.00
	63	Placebo	Male	Severity of illness	6.00	6.00	4.00	4.00	3.00	2.00	2.00
				Global improvement		4.00	3.00	3.00	2.00	1.00	1.00
				Efficacy index		13.00	9.00	5.00	5.00	5.00	1.00
				Efficacy index (*)		1.00	2.00	2.00	3.00	4.00	4.00

1501

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill.
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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8

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	64	Placebo	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		3.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		9.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)	2.00	1.00	1.00	1.00	1.00	1.00	
	65	Reboxetine	Male	Severity of illness	6.00	5.00	4.00	3.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index		9.00	5.00	5.00	1.00	1.00	1.00
				Efficacy index (*)	2.00	3.00	3.00	4.00	4.00	4.00	
	66	Reboxetine	Male	Severity of illness	4.00	4.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		4.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index (*)	1.00	3.00	3.00	3.00	3.00	3.00	
150	139	Imipramine	Male	Severity of illness	4.00	4.00	6.00				
				Global improvement		5.00	6.00				
				Efficacy index		14.00	13.00				
				Efficacy index (*)	0.50	1.00					
	140	Placebo	Male	Severity of illness	4.00	4.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		4.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)	1.00	3.00	4.00	4.00	4.00	4.00	
	141	Placebo	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	9.00	5.00	5.00	5.00	5.00
				Efficacy index (*)	1.00	2.00	3.00	3.00	3.00	3.00	
	142	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.00	
	143	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index (*)	2.00	2.00	2.00	2.00	2.00	1.53	

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SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

9

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/1	144	Reboxetine	Female	Severity of illness	5.00	5.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		5.00	2.00	2.00	1.00	1.00	
				Efficacy index		14.00	6.00	2.00	2.00	2.00	
				Efficacy index (*)		0.50	1.50				
451		Reboxetine	Female	Severity of illness	5.00	5.00	6.00				
				Global improvement		4.00	6.00				
				Efficacy index		14.00	15.00				
				Efficacy index (*)		0.50	0.33				
452		Placebo	Male	Severity of illness	4.00	4.00	2.00	1.00	1.00	2.00	1.00
				Global improvement		3.00	1.00	1.00	1.00	2.00	1.00
				Efficacy index		9.00	1.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		2.00	4.00	2.00	2.00	2.00	2.00
453		Imipramine	Female	Severity of illness	4.00	3.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		10.00	10.00	6.00	6.00	6.00	6.00
				Efficacy index (*)		1.00	1.00	1.50	1.50	1.50	1.50
454		Reboxetine	Male	Severity of illness	4.00	3.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		6.00	6.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.50	1.50	2.00	2.00	2.00	2.00
455		Placebo	Female	Severity of illness	5.00	5.00	4.00	3.00	4.00	4.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		13.00	9.00	5.00	9.00	9.00	5.00
				Efficacy index (*)		1.00	2.00	3.00	2.00	2.00	3.00
456		Imipramine	Female	Severity of illness	4.00	4.00	4.00				
				Global improvement		3.00	3.00				
				Efficacy index		10.00	12.00				
				Efficacy index (*)		1.00	0.50				
3/2	65/A	Reboxetine	Female	Severity of illness	6.00	5.00	4.00	5.00	5.00	5.00	5.00
				Global improvement		3.00	2.00	3.00	3.00	3.00	3.00
				Efficacy index		10.00	6.00	10.00	9.00	9.00	9.00
				Efficacy index (*)		1.00	1.50	1.00	2.00	2.00	2.00

15703

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=moderately ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill, 8=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=initially improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

10

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/3	67	Placebo	Male	Severity of illness	5.00	5.00	5.00	4.00	3.00	3.00	4.00
				Global improvement		3.00	4.00	3.00	2.00	2.00	2.00
				Efficacy index		9.00	13.00	5.00	6.00	6.00	6.00
				Efficacy index (*)		2.00	1.00	3.00	1.50	1.50	
68	Reboxetine	Male	Severity of illness	5.00	4.00	3.00	1.00	1.00	1.00	1.00	1.00
			Global improvement		2.00	2.00	1.00	1.00	1.00	1.00	
			Efficacy index		6.00	5.00	2.00	2.00	2.00	2.00	
				Efficacy index (*)		1.50	3.00	2.00	2.00	2.00	
69	Placebo	Male	Severity of illness	5.00	5.00	4.00	3.00	3.00	6.00	4.00	3.00
			Global improvement		5.00	2.00	2.00	6.00	2.00	2.00	
			Efficacy index		15.00	6.00	5.00	45.00	6.00	5.00	
				Efficacy index (*)		0.33	1.50	3.00	0.33	1.50	
70	Imipramine	Male	Severity of illness	6.00	5.00	4.00	2.00	2.00	4.00	2.00	2.00
			Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	
			Efficacy index		10.00	6.00	2.00	6.00	2.00	2.00	
				Efficacy index (*)		1.00	1.50	2.00	1.50	2.00	
71	Imipramine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00	3.00	2.00	2.00
			Global improvement		2.00	2.00	2.00	2.00	2.00	2.00	
			Efficacy index		6.00	6.00	2.00	2.00	2.00	2.00	
				Efficacy index (*)		1.50	1.50	2.00	2.00	2.00	
72	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	2.00	2.00	3.00	3.00	4.00
			Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	
			Efficacy index		5.00	5.00	1.00	5.00	5.00	5.00	
				Efficacy index (*)		3.00	3.00	4.00	3.00	3.00	
3/4	79	Imipramine	Female	Severity of illness	5.00	5.00	5.00	3.00	3.00	2.00	2.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		6.00	6.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.50	1.50	2.00	2.00	2.00	
80	Imipramine	Male	Severity of illness	5.00	5.00	4.00	3.00	3.00	3.00	2.00	2.00
			Global improvement		3.00	2.00	2.00	2.00	2.00	1.00	
			Efficacy index		3.00	6.00	4.00	4.00	4.00	5.00	
				Efficacy index (*)		2.00	1.50	1.00	1.50	1.00	

1504

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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11

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centro	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/4	81	Reboxetine	Female	Severity of illness	6.00	4.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	4.00	4.00	1.00	1.00	2.00
				Efficacy index		5.00	4.00	4.00	1.00	1.00	4.00
				Efficacy index (*)		3.00	4.00	4.00	4.00	4.00	4.00
	82	Placebo	Male	Severity of illness	4.00	4.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	6.00	5.00	5.00	5.00
				Efficacy index (*)		2.00	3.00	1.50	3.00	3.00	3.00
	83	Placebo	Male	Severity of illness	4.00	5.00					
				Global improvement		6.00					
				Efficacy index		16.00					
				Efficacy index (*)		0.25					
	84	Reboxetine	Female	Severity of illness	5.00	4.00	2.00	1.00	1.00	1.00	1.00
				Global improvement		2.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		5.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	4.00	4.00	4.00	4.00	4.00
	85	Imipramine	Female	Severity of illness	5.00	3.00	3.00	3.00	3.00	3.00	2.00
				Global improvement		3.00	2.00	2.00	3.00	2.00	2.00
				Efficacy index		6.00	5.00	6.00	10.00	6.00	2.00
				Efficacy index (*)		1.50	3.00	1.50	1.00	1.50	2.00
	86	Imipramine	Male	Severity of illness	5.00	4.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		5.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	3.00	4.00	4.00	4.00	4.00
	87	Placebo	Female	Severity of illness	5.00	5.00	5.00	4.00	6.00	5.00	4.00
				Global improvement		3.00	2.00	2.00	6.00	2.00	2.00
				Efficacy index		9.00	5.00	5.00	14.00	6.00	6.00
				Efficacy index (*)		2.00	3.00	3.00	0.50	1.50	1.50
	88	Placebo	Male	Severity of illness	5.00	4.00	4.00	3.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		6.00	6.00	5.00	1.00	1.00	1.00
				Efficacy index (*)		1.50	1.50	3.00	4.00	4.00	4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

15051

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12

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3/4	89	Reboxetine	Female	Severity of illness	6.00	5.00	5.00	5.00	4.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		5.00	5.00	6.00	6.00	6.00	6.00
				Efficacy index (*)	3.00	3.00	3.00	1.50	1.50	1.50	
90	90	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	2.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		14.00	10.00	6.00	6.00	6.00	6.00
				Efficacy index (*)	0.50	1.00	1.50	1.50	1.50	2.00	
457	457	Placebo	Female	Severity of illness	5.00	6.00	5.00	6.00	6.00	5.00	5.00
				Global improvement		5.00	4.00	5.00	5.00	4.00	5.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.00	
458	458	Reboxetine	Female	Severity of illness	5.00	6.00	6.00	6.00	6.00	6.00	6.00
				Global improvement		5.00	6.00	6.00	6.00	6.00	6.00
				Efficacy index		14.00	14.00	14.00	14.00	14.00	14.00
				Efficacy index (*)	0.50	0.50	0.50	0.50	0.50	0.50	
459	459	Placebo	Female	Severity of illness	5.00	4.00	4.00	4.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		6.00	6.00	6.00	6.00	6.00	6.00
				Efficacy index (*)	1.50	1.50	1.50	1.50	1.50	2.00	
460	460	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		16.00	16.00	16.00	16.00	16.00	16.00
				Efficacy index (*)	0.25	0.25	0.25	0.25	0.25	0.25	
461	461	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		12.00	12.00	12.00	12.00	12.00	12.00
				Efficacy index (*)	0.50	0.50	0.50	0.50	0.50	0.50	
462	462	Imipramine	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		8.00	8.00	8.00	8.00	8.00	8.00
				Efficacy index (*)	0.75	0.75	0.75	0.75	0.75	0.75	

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1506

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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13

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	91	Imipramine	Female	Severity of illness	6.00	6.00	6.00	5.00	5.00	5.00	3.00
				Global improvement		4.00	4.00	4.00	3.00	3.00	2.00
				Efficacy index	15.00	14.00	14.00	10.00	10.00	6.00	
				Efficacy index (*)	0.33	0.50	0.50	1.00	1.00	1.50	
	92	Reboxetine	Female	Severity of illness	6.00	6.00	6.00	6.00	6.00	6.00	6.00
				Global improvement		5.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index	13.00	13.00	13.00	13.00	13.00	13.00	
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.00	
	93	Placebo	Male	Severity of illness	4.00	4.00	5.00	5.00	2.00	2.00	1.00
				Global improvement		5.00	6.00	5.00	1.00	1.00	1.00
				Efficacy index	14.00	14.00	14.00	1.00	1.00	1.00	
				Efficacy index (*)	0.50	0.50	0.50	4.00	4.00	4.00	
	94	Placebo	Female	Severity of illness	5.00	5.00	4.00	4.00	1.00	1.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index	13.00	9.00	5.00	5.00	5.00	1.00	
				Efficacy index (*)	1.00	2.00	3.00	3.00	4.00	4.00	
	95	Imipramine	Female	Severity of illness	5.00	2.00	2.00	2.00	2.00	1.00	1.00
				Global improvement		2.00	2.00	2.00	2.00	1.00	1.00
				Efficacy index	5.00	5.00	5.00	5.00	5.00	1.00	
				Efficacy index (*)	3.00	3.00	3.00	3.00	4.00	4.00	
	96	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	3.00	2.00	2.00	2.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index	9.00	9.00	9.00	5.00	1.00	1.00	
				Efficacy index (*)	2.00	2.00	3.00	4.00	4.00	4.00	
115		Reboxetine	Female	Severity of illness	5.00	4.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index	9.00	5.00	5.00	5.00	5.00	1.00	
				Efficacy index (*)	2.00	2.00	3.00	4.00	4.00	4.00	
116		Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	2.00	2.00	2.00
				Global improvement		4.00	4.00	4.00	2.00	2.00	2.00
				Efficacy index	15.00	15.00	15.00	1.00	1.00	1.00	
				Efficacy index (*)	0.33	0.33	0.33	4.00	4.00	4.00	

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1507

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=moderately ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

14

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	117	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 2.00 6.00 1.50	4.00 2.00 2.00 2.00	3.00 2.00 2.00 2.00	2.00 2.00 2.00 2.00	2.00 2.00 2.00 2.00	2.00 2.00 2.00 2.00	2.00 2.00 2.00 2.00
	118	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 13.00 1.00	5.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	3.00 2.00 5.00 3.00	2.00 2.00 1.00 4.00	2.00 2.00 1.00 4.00	2.00 2.00 1.00 4.00
	119	Placebo	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	3.00 3.00 3.00 3.00	3.00 3.00 3.00 3.00	3.00 3.00 3.00 3.00	3.00 3.00 3.00 3.00	3.00 3.00 3.00 3.00	3.00 3.00 3.00 3.00	3.00 3.00 3.00 3.00
	120	Placebo	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 3.00 9.00 2.00	5.00 2.00 9.00 2.00	4.00 2.00 9.00 3.00	3.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00
	145	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 2.00 4.00 4.00	4.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	2.00 2.00 1.00 4.00
	146	Placebo	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 3.00 9.00 2.00	5.00 2.00 9.00 2.00	4.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	2.00 2.00 1.00 4.00	2.00 2.00 1.00 4.00
	147	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 3.00 9.00 2.00	6.00 3.00 9.00 2.00	5.00 3.00 9.00 2.00	5.00 3.00 9.00 2.00	4.00 2.00 5.00 3.00	4.00 2.00 5.00 3.00	4.00 2.00 5.00 3.00
	148	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 3.00 9.00 2.00	5.00 3.00 9.00 2.00	5.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	4.00 2.00 5.00 3.00	4.00 2.00 5.00 3.00	3.00 2.00 5.00 3.00

1508

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SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=initially improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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15

PHARMACIA CNS R2D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/1	149	Reboxetine	Male	Severity of illness	6.00	6.00	5.00	4.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index	15.00	11.00	10.00	5.00	1.00	1.00	
				Efficacy index (*)	0.33	0.67					
4/2	93/A	Placebo	Male	Severity of illness	6.00	5.00	5.00	4.00	4.00	4.00	4.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index	9.00	9.00	5.00	1.00	1.00	1.00	
				Efficacy index (*)	2.00	2.00					
4/2	99/A	Placebo	Male	Severity of illness	6.00	6.00	5.00	3.00	2.00	1.00	1.00
				Global improvement		4.00	4.00	2.00	2.00	1.00	1.00
				Efficacy index	13.00	13.00	5.00	1.00	1.00	1.00	
				Efficacy index (*)	1.00	1.00					
4/3	97	Placebo	Male	Severity of illness	5.00	5.00	4.00	4.00	3.00	1.00	1.00
				Global improvement		5.00	2.00	3.00	3.00	1.00	1.00
				Efficacy index	13.00	5.00	5.00	3.00	3.00	1.00	
				Efficacy index (*)	1.00	3.00					
4/3	104	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	3.00	3.00	5.00	5.00	5.00
				Efficacy index	13.00	9.00	9.00	13.00	13.00	13.00	
				Efficacy index (*)	1.00	2.00					
4/3	98	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	5.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	5.00	6.00	6.00
				Efficacy index	13.00	13.00	13.00	13.00	13.00	13.00	
				Efficacy index (*)	1.00	1.00					
4/3	99	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	5.00	5.00
				Global improvement		3.00	3.00	2.00	3.00	6.00	6.00
				Efficacy index	13.00	13.00	9.00	9.00	13.00	13.00	
				Efficacy index (*)	1.00	1.00					
4/3	99	Placebo	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		5.00	6.00	6.00	6.00	6.00	6.00
				Efficacy index	15.00	15.00	15.00	15.00	15.00	15.00	
				Efficacy index (*)	0.33	0.33					

1509

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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16

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16,0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/3	100	Imipramine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00		
				Global improvement		3.00	6.00	6.00			
				Efficacy index		7.00	15.00	16.00			
				Efficacy index (*)		1.00	0.33	0.25			
	101	Imipramine	Male	Severity of illness	5.00	5.00	4.00	3.00	2.00	2.00	2.00
				Global improvement		4.00	3.00	2.00	2.00	1.00	1.00
				Efficacy index		13.00	9.00	5.00	1.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	3.00	4.00	4.00	4.00
4/4	109	Reboxetine	Female	Severity of illness	5.00	4.00	3.00	2.00	2.00	1.00	1.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		10.00	6.00	2.00	2.00	4.00	4.00
				Efficacy index (*)		1.00	1.50	2.00	2.00	4.00	4.00
15	110	Imipramine	Male	Severity of illness	6.00	5.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	4.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	5.00	6.00	6.00	6.00
				Efficacy index (*)		2.00	2.00	3.00	1.50	1.50	1.50
10	111	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	5.00	6.00	6.00	6.00	5.00
				Efficacy index (*)		1.00	3.00	1.50	1.50	1.50	3.00
	112	Placebo	Male	Severity of illness	5.00	4.00	4.00	3.00	3.00	4.00	4.00
				Global improvement		3.00	3.00	2.00	2.00	3.00	3.00
				Efficacy index		9.00	9.00	5.00	5.00	9.00	9.00
				Efficacy index (*)		2.00	2.00	3.00	3.00	2.00	2.00
	113	Reboxetine	Male	Severity of illness	5.00	5.00	4.00	4.00	3.00	3.00	2.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		13.00	9.00	9.00	5.00	5.00	1.00
				Efficacy index (*)		1.00	2.00	2.00	3.00	3.00	4.00
	114	Placebo	Female	Severity of illness	4.00	4.00	3.00	3.00	3.00	3.00	2.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		14.00	10.00	9.00	9.00	6.00	6.00
				Efficacy index (*)		0.50	1.00	2.00	2.00	1.50	2.00

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1510

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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17

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
4/4	175	Imipramine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00	2.00	1.00
				Global improvement		3.00	2.00	2.00	2.00	1.00	1.00
				Efficacy index	10.00	6.00	6.00	6.00	2.00	2.00	
				Efficacy index (*)	1.00	1.50	1.50	1.50	2.00	2.00	
	176	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	7.00		
				Global improvement		4.00	3.00	3.00	7.00		
				Efficacy index	13.00	10.00	10.00	14.00			
				Efficacy index (*)	1.00	1.00	1.00	0.50			
	177	Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00		
				Global improvement		4.00	3.00	3.00			
				Efficacy index	14.00	10.00	11.00				
				Efficacy index (*)	0.50	1.00	0.67				
	178	Reboxetine	Female	Severity of illness	5.00	4.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index	9.00	5.00	2.00	2.00	2.00	2.00	
				Efficacy index (*)	2.00	3.00	2.00	2.00	2.00	2.00	
	179	Placebo	Female	Severity of illness	5.00	5.00	4.00	6.00	6.00		
				Global improvement		4.00	3.00	6.00			
				Efficacy index	14.00	6.00	16.00				
				Efficacy index (*)	0.50	1.50	0.25				
	180	Reboxetine	Male	Severity of illness	5.00	5.00	4.00	3.00	3.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	1.00	1.00
				Efficacy index	9.00	5.00	5.00	5.00	2.00	2.00	
				Efficacy index (*)	2.00	3.00	3.00	2.00	2.00	4.00	
5/1	127	Reboxetine	Male	Severity of illness	5.00	4.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index	9.00	9.00	10.00	14.00	10.00	10.00	
				Efficacy index (*)	2.00	2.00	1.00	0.50	1.00	1.00	
	128	Reboxetine	Female	Severity of illness	5.00	2.00	2.00	2.00	2.00	1.00	1.00
				Global improvement		1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index	2.00	2.00	2.00	2.00	1.00	1.00	
				Efficacy index (*)	2.00	2.00	2.00	2.00	4.00	4.00	

1511

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SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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18

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PHARMACIA CNS R&D
 ROBEXETINE - PROTOCOL 20124/015
 Listing No.: 16.0
 CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
5/1	129	Placebo	Male	Severity of illness	5.00	5.00	4.00	3.00	2.00	3.00	4.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	3.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	9.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	2.00	2.00
	130	Placebo	Male	Severity of illness	5.00	5.00	5.00	5.00	2.00	2.00	3.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	9.00	5.00	1.00	5.00
				Efficacy index (*)		2.00	3.00	2.00	3.00	4.00	3.00
	131	Imipramine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		9.00	5.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	4.00	4.00
	132	Imipramine	Male	Severity of illness	5.00	2.00	1.00	1.00	1.00	1.00	1.00
				Global improvement		2.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		1.00	1.00	1.00	2.00	2.00	2.00
				Efficacy index (*)		4.00	4.00	4.00	2.00	2.00	2.00
5/2	121	Imipramine	Female	Severity of illness	5.00	5.00	5.00	3.00	4.00	4.00	5.00
				Global improvement		3.00	4.00	2.00	5.00	4.00	5.00
				Efficacy index		9.00	9.00	5.00	13.00	9.00	13.00
				Efficacy index (*)		2.00	2.00	3.00	1.00	2.00	1.00
	125	Roboxetine	Male	Severity of illness	5.00	5.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		4.00	1.00	1.00	1.00	2.00	1.00
				Efficacy index		13.00	1.00	2.00	2.00	6.00	2.00
				Efficacy index (*)		1.00	4.00	2.00	2.00	1.50	2.00
5/3	133	Placebo	Male	Severity of illness	5.00	5.00	6.00				
				Global improvement		5.00	6.00				
				Efficacy index		13.00	13.00				
				Efficacy index (*)		1.00	1.00				
	134	Roboxetine	Female	Severity of illness	4.00	4.00	2.00	3.00	1.00	1.00	1.00
				Global improvement		4.00	2.00	3.00	1.00	1.00	1.00
				Efficacy index		13.00	2.00	10.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	2.00	1.00	2.00	2.00	2.00

1512

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
 GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
 EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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19

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
5/3	135	Imipramine	Female	Severity of illness	3.00	2.00	1.00	1.00	2.00	3.00	4.00
				Global improvement		3.00	1.00	1.00	2.00	3.00	4.00
				Efficacy index		5.00	2.00	2.00	2.00	6.00	14.00
				Efficacy index (*)		3.00	2.00	2.00	1.50	0.50	
	136	Imipramine	Female	Severity of illness	5.00	4.00	2.00	1.00	2.00	1.00	1.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		10.00	6.00	2.00	2.00	2.00	4.00
				Efficacy index (*)		1.00	1.50	2.00	2.00	1.00	
	137	Reboxetine	Female	Severity of illness	4.00	3.00	2.00	2.00	2.00	1.00	1.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		5.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		3.00	2.00	2.00	2.00	2.00	
	138	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	
6/1	151	Imipramine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		12.00	12.00	12.00	12.00	12.00	12.00
				Efficacy index (*)		0.50	0.50	0.50	0.50	0.50	
	152	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00	4.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		14.00	10.00	10.00	10.00	5.00	1.00
				Efficacy index (*)		0.50	1.00	1.00	1.50	3.00	
	153	Reboxetine	Male	Severity of illness	5.00	5.00	4.00	4.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		14.00	10.00	10.00	6.00	6.00	6.00
				Efficacy index (*)		0.50	1.00	1.00	1.50	1.50	
	154	Imipramine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		14.00	10.00	10.00	6.00	6.00	6.00
				Efficacy index (*)		0.50	1.00	1.00	1.50	1.50	

14
51
13

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/1	155	Placebo	Male	Severity of illness	6.00	6.00	6.00	6.00	6.00	6.00	6.00
				Global improvement	4.00	4.00	4.00	3.00	4.00	4.00	
				Efficacy index	13.00	14.00	14.00	10.00	14.00	14.00	
				Efficacy index (*)	1.00	0.50	1.00	1.00	0.50		
	156	Placebo	Female	Severity of illness	5.00	4.00	3.00	3.00	2.00	2.00	2.00
				Global improvement	4.00	4.00	3.00	2.00	2.00	2.00	
				Efficacy index	14.00	10.00	10.00	5.00	5.00	5.00	
				Efficacy index (*)	0.50	1.00	3.00	3.00	4.00	3.00	
6/2	157	Reboxetine	Male	Severity of illness	4.00	3.00	2.00	2.00	2.00	2.00	2.00
				Global improvement	4.00	4.00	3.00	3.00	2.00	2.00	
				Efficacy index	15.00	10.00	10.00	10.00	5.00	5.00	
				Efficacy index (*)	0.33	1.00	1.00	1.00	3.00	3.00	
	158	Imipramine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	1.00
				Global improvement	4.00	4.00	3.00	3.00	2.00	2.00	
				Efficacy index	13.00	9.00	6.00	6.00	6.00	5.00	
				Efficacy index (*)	1.00	2.00	1.50	1.50	3.00	4.00	
	159	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	3.00	3.00	3.00
				Global improvement	4.00	4.00	3.00	3.00	2.00	2.00	
				Efficacy index	13.00	9.00	9.00	9.00	5.00	5.00	
				Efficacy index (*)	1.00	2.00	2.00	2.00	3.00	3.00	
	160	Placebo	Male	Severity of illness	5.00	3.00	3.00	2.00	2.00	3.00	5.00
				Global improvement	2.00	2.00	2.00	2.00	2.00	3.00	
				Efficacy index	6.00	6.00	6.00	6.00	6.00	10.00	
				Efficacy index (*)	1.50	1.50	1.50	1.50	1.50	1.00	
	161	Reboxetine	Female	Severity of illness	6.00	6.00	3.00	3.00	3.00	3.00	3.00
				Global improvement	4.00	4.00	3.00	3.00	3.00	3.00	
				Efficacy index	14.00	6.00	6.00	6.00	6.00	6.00	
				Efficacy index (*)	0.50	1.50	1.50	1.50	1.50	1.50	
	162	Placebo	Male	Severity of illness	5.00	5.00					
				Global improvement	4.00	4.00					
				Efficacy index	13.00	13.00					
				Efficacy index (*)	1.00						

1514

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=moderately ill, 4=markedly ill, 5=severely ill, 6=extremely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

21

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.9

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/2	169	Imipramine	Female	Severity of illness	7.00	1.00	6.00	7.00			
				Global improvement		1.00	5.00	6.00			
				Efficacy index		2.00	13.00	13.00			
				Efficacy index (*)		2.00	1.00				
	170	Placebo	Male	Severity of illness	6.00	3.00					
				Global improvement		1.00					
				Efficacy index		1.00					
				Efficacy index (*)		4.00					
	171	Imipramine	Female	Severity of illness	5.00	5.00	4.00	1.00	1.00	1.00	1.00
				Global improvement		4.00	2.00	1.00	1.00	1.00	
				Efficacy index		13.00	6.00	2.00	2.00	2.00	
				Efficacy index (*)		1.00	1.50	2.00	2.00	2.00	
	172	Reboxetine	Female	Severity of illness	6.00	5.00	5.00	5.00	6.00	6.00	6.00
				Global improvement		4.00	4.00	4.00	5.00	5.00	
				Efficacy index		13.00	14.00	14.00	14.00	14.00	
				Efficacy index (*)		1.00	0.50	0.50	0.50	0.50	
	173	Placebo	Male	Severity of illness	5.00	5.00	5.00	5.00	6.00	4.00	5.00
				Global improvement		4.00	4.00	4.00	6.00	3.00	
				Efficacy index		13.00	13.00	13.00	13.00	5.00	
				Efficacy index (*)		1.00	1.00	1.00	1.00	4.00	
	174	Reboxetine	Male	Severity of illness	6.00	2.00	1.00	1.00	1.00	1.00	4.00
				Global improvement		1.00	1.00	1.00	1.00	1.00	
				Efficacy index		4.00	4.00	4.00	4.00	4.00	
				Efficacy index (*)		4.00	4.00	4.00	4.00	2.00	
6/3	163	Reboxetine	Male	Severity of illness	5.00	5.00					
				Global improvement		4.00					
				Efficacy index		15.00					
				Efficacy index (*)		0.33					
	164	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	4.00	4.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	
				Efficacy index		14.00	10.00	9.00	9.00	6.00	
				Efficacy index (*)		0.50	1.00	2.00	2.00	1.50	

1515

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

22

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
6/3	165	Imipramine	Female	Severity of illness	6.00	4.00	5.00	4.00	4.00	3.00	3.00	
				Global improvement		3.00	3.00	3.00	3.00	3.00	2.00	
				Efficacy index		10.00	10.00	10.00	10.00	9.00	6.00	
				Efficacy index (*)		1.00	1.00	1.00	1.00	2.00	1.50	
166	Reboxetine	Female	Severity of illness	6.00	6.00							
			Global improvement		6.00							
			Efficacy index		15.00							
				Efficacy index (*)		0.33						
167	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	2.00	2.00	2.00	
			Global improvement		4.00	3.00	3.00	2.00	2.00	2.00		
			Efficacy index		15.00	10.00	9.00	5.00	1.00	1.00		
				Efficacy index (*)		0.33	1.00	2.00	3.00	4.00		
168	Placebo	Female	Severity of illness	6.00	5.00	5.00	5.00	5.00	5.00	6.00	6.00	
			Global improvement		3.00	3.00	3.00	3.00	6.00	6.00		
			Efficacy index		10.00	10.00	9.00	10.00	15.00	15.00		
				Efficacy index (*)		1.00	1.00	2.00	1.00	0.33		
505	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	
			Global improvement		6.00	4.00	4.00	4.00	4.00	4.00		
			Efficacy index		14.00	16.00	16.00	16.00	16.00	16.00		
				Efficacy index (*)		0.50	0.25					
506	Placebo	Female	Severity of illness	5.00	4.00	4.00	5.00	4.00	4.00	3.00	3.00	4.00
			Global improvement		4.00	5.00	4.00	4.00	3.00	3.00		
			Efficacy index		13.00	13.00	14.00	11.00	11.00	11.00		
				Efficacy index (*)		1.00	1.00	0.50	0.67	0.67		
507	Imipramine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	2.00	1.00	
			Global improvement		3.00	2.00	2.00	2.00	2.00	2.00		
			Efficacy index		10.00	15.00	6.00	6.00	2.00	2.00		
				Efficacy index (*)		1.00	0.33	1.50	1.50	2.00		
508	Reboxetine	Female	Severity of illness	5.00	3.00	4.00	3.00	3.00	3.00	2.00	2.00	
			Global improvement		3.00	3.00	3.00	3.00	2.00	2.00		
			Efficacy index		9.00	10.00	10.00	10.00	2.00	1.00		
				Efficacy index (*)		2.00	2.00	1.00	1.00	2.00		

1516

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

23

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
6/3	509	Placebo	Male	Severity of illness	4.00	3.00	3.00	3.00	3.00	3.00	2.00
				Global improvement		2.00	2.00	3.00	2.00	2.00	2.00
				Efficacy index		5.00	5.00	10.00	6.00	6.00	5.00
				Efficacy index (*)		3.00	3.00	1.00	1.50	1.50	3.00
	510	Reboxetine	Female	Severity of illness	4.00	4.00	3.00				
				Global improvement		3.00	3.00				
				Efficacy index		10.00	12.00				
				Efficacy index (*)		1.00	0.50				
	511	Imipramine	Female	Severity of illness	4.00	3.00	3.00	3.00	3.00	3.00	5.00
				Global improvement		3.00	2.00	2.00	2.00	6.00	6.00
				Efficacy index		11.00	6.00	6.00	5.00	16.00	16.00
				Efficacy index (*)		0.67	1.50	1.50	3.00	0.25	
	512	Placebo	Female	Severity of illness	4.00	4.00					
				Global improvement		4.00					
				Efficacy index		16.00					
				Efficacy index (*)		0.25					
	513	Imipramine	Female	Severity of illness	5.00	4.00	3.00	2.00	2.00	2.00	1.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		11.00	7.00	6.00	2.00	2.00	2.00
				Efficacy index (*)		0.67	1.00	1.50	2.00	2.00	
7/02	181	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	4.00
				Global improvement		5.00	5.00	4.00	4.00	3.00	3.00
				Efficacy index		13.00	13.00	13.00	13.00	9.00	10.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	2.00	
	182	Placebo	Male	Severity of illness	5.00	4.00	3.00	3.00	4.00	3.00	3.00
				Global improvement		4.00	3.00	4.00	3.00	3.00	3.00
				Efficacy index		13.00	9.00	13.00	9.00	9.00	9.00
				Efficacy index (*)		1.00	2.00	1.00	2.00	2.00	
	183	Imipramine	Male	Severity of illness	5.00	4.00	5.00	6.00			
				Global improvement		4.00	5.00	6.00			
				Efficacy index		11.00	15.00	16.00			
				Efficacy index (*)		0.67	0.33	0.25			

1517

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

24

9550082

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
7/02	184	Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	3.00	2.00	2.00	
				Global improvement		4.00	3.00	2.00	1.00	1.00	1.00	
				Efficacy index		13.00	9.00	5.00	1.00	1.00	1.00	
				Efficacy index (*)		1.00	2.00	3.00	4.00	4.00	4.00	
185	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00			
			Global improvement		5.00	5.00	5.00	4.00				
			Efficacy index		16.00	16.00	16.00	16.00				
				Efficacy index (*)		0.25	0.25	0.25	0.25			
186	Placebo	Male	Severity of illness	4.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	2.00
			Global improvement		3.00	3.00	3.00	3.00	3.00	2.00		
			Efficacy index		10.00	10.00	10.00	10.00	10.00	6.00		
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.50	
535	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
			Global improvement		5.00	6.00	4.00	4.00	4.00	3.00		
			Efficacy index		13.00	13.00	13.00	13.00	13.00	9.00		
				Efficacy index (*)		1.00	1.00	1.00	1.00	2.00	2.00	
536	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	4.00	3.00	3.00	3.00	3.00	3.00
			Global improvement		3.00	3.00	3.00	2.00	2.00	2.00		
			Efficacy index		9.00	5.00	5.00	5.00	5.00	5.00		
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	3.00	
7/03	187	Imipramine	Female	Severity of illness	6.00	5.00	4.00	4.00	4.00	2.00	2.00	
				Global improvement		4.00	3.00	4.00	3.00	2.00	1.00	
				Efficacy index		13.00	9.00	13.00	9.00	5.00	1.00	
				Efficacy index (*)		1.00	2.00	1.00	2.00	3.00	4.00	
188	Placebo	Male	Severity of illness	5.00	5.00	5.00	3.00	3.00	3.00	3.00	3.00	4.00
			Global improvement		4.00	4.00	2.00	2.00	2.00	2.00		
			Efficacy index		13.00	13.00	1.00	5.00	5.00	5.00		
				Efficacy index (*)		1.00	1.00	4.00	3.00	3.00	3.00	
189	Placebo	Male	Severity of illness	5.00	5.00	4.00	4.00	2.00	2.00	3.00	3.00	3.00
			Global improvement		4.00	2.00	2.00	2.00	2.00	2.00		
			Efficacy index		13.00	5.00	5.00	5.00	5.00	5.00		
				Efficacy index (*)		1.00	3.00	3.00	3.00	3.00	3.00	

1518

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

25

9550082

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	190	Reboxetine	Male	Severity of illness	5.00	5.00	3.00	3.00	2.00	4.00	4.00
				Global improvement		5.00	4.00	2.00	2.00	4.00	4.00
				Efficacy index		14.00	9.00	5.00	5.00	9.00	9.00
				Efficacy index (*)		0.50	2.00	3.00	3.00	2.00	2.00
	191	Imipramine	Female	Severity of illness	5.00	3.00	5.00	3.00	3.00	5.00	5.00
				Global improvement		3.00	4.00	2.00	3.00	4.00	4.00
				Efficacy index		9.00	9.00	5.00	9.00	9.00	9.00
				Efficacy index (*)		2.00	2.00	3.00	2.00	2.00	2.00
	192	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	3.00	5.00	5.00	5.00
				Global improvement		4.00	3.00	2.00	3.00	3.00	3.00
				Efficacy index		13.00	9.00	5.00	9.00	9.00	9.00
				Efficacy index (*)		1.00	2.00	3.00	2.00	2.00	2.00
	523	Reboxetine	Female	Severity of illness	6.00	5.00	5.00	3.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	3.00	2.00	2.00	2.00
				Efficacy index		13.00	13.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		4.00	1.00	3.00	3.00	3.00	3.00
	524	Placebo	Female	Severity of illness	5.00	5.00	5.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	3.00
				Efficacy index		13.00	13.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	3.00	3.00	3.00	3.00
	525	Placebo	Female	Severity of illness	6.00	6.00	5.00	3.00	3.00	3.00	2.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		13.00	9.00	9.00	5.00	5.00	5.00
				Efficacy index (*)		1.00	2.00	2.00	3.00	3.00	3.00
	526	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	3.00	3.00
				Global improvement		4.00	4.00	4.00	4.00	2.00	2.00
				Efficacy index		13.00	13.00	13.00	13.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	3.00	3.00
	527	Imipramine	Female	Severity of illness	6.00	6.00	6.00	6.00	3.00	3.00	3.00
				Global improvement		4.00	4.00	4.00	3.00	3.00	3.00
				Efficacy index		13.00	13.00	13.00	9.00	9.00	9.00
				Efficacy index (*)		1.00	1.00	1.00	2.00	2.00	2.00

15119

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

26

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/03	528	Imipramine	Female	Severity of illness	5.00	3.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	
				Efficacy index		13.00	13.00	13.00	13.00	13.00	
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	
7/04	193	Placebo	Female	Severity of illness	5.00	5.00	5.00	4.00	2.00	2.00	2.00
				Global improvement		4.00	4.00	2.00	2.00	2.00	
				Efficacy index		13.00	13.00	9.00	1.00	5.00	1.00
				Efficacy index (*)		1.00	1.00	2.00	4.00	3.00	4.00
194		Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	3.00	2.00	2.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	
				Efficacy index		13.00	9.00	9.00	5.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	2.00	3.00	4.00	4.00
195		Placebo	Female	Severity of illness	5.00	5.00	5.00	4.00	2.00	3.00	2.00
				Global improvement		4.00	4.00	3.00	2.00	2.00	
				Efficacy index		14.00	13.00	3.00	1.00	5.00	1.00
				Efficacy index (*)		0.50	1.00	2.00	4.00	3.00	4.00
196		Reboxetine	Female	Severity of illness	5.00	5.00	5.00	3.00	3.00	3.00	2.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	
				Efficacy index		13.00	13.00	9.00	5.00	1.00	1.00
				Efficacy index (*)		1.00	1.00	2.00	3.00	3.00	4.00
197		Imipramine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	
				Efficacy index		14.00	13.00	13.00	14.00	13.00	
				Efficacy index (*)		0.50	1.00	1.00	0.50	1.00	1.00
198		Imipramine	Female	Severity of illness	5.00	5.00	5.00	3.00	3.00	2.00	2.00
				Global improvement		4.00	4.00	2.00	2.00	2.00	
				Efficacy index		13.00	13.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		1.00	1.00	3.00	3.00	3.00	4.00
199		Imipramine	Male	Severity of illness	5.00	5.00	5.00	5.00	4.00	4.00	3.00
				Global improvement		4.00	3.00	4.00	2.00	3.00	
				Efficacy index		13.00	10.00	13.00	5.00	5.00	
				Efficacy index (*)		1.00	1.00	1.00	3.00	3.00	3.00

1520

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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27

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/04	200	Placebo	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	4.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	3.00
				Efficacy index		13.00	13.00	9.00	5.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	2.00	2.00	3.00	3.00
	201	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	2.00
				Global improvement		4.00	4.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	13.00	5.00	6.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	3.00	1.50	3.00	3.00
	202	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	3.00
				Global improvement		4.00	4.00	3.00	4.00	2.00	2.00
				Efficacy index		13.00	13.00	9.00	13.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	2.00	1.00	3.00	3.00
	203	Placebo	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	3.00
				Global improvement		4.00	4.00	4.00	3.00	2.00	2.00
				Efficacy index		13.00	13.00	13.00	9.00	13.00	5.00
				Efficacy index (*)		1.00	1.00	2.00	1.00	3.00	3.00
	204	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	3.00
				Global improvement		4.00	4.00	4.00	3.00	3.00	3.00
				Efficacy index		13.00	13.00	13.00	9.00	9.00	9.00
				Efficacy index (*)		1.00	1.00	1.00	2.00	2.00	2.00
7/05	205	Placebo	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	14.00	14.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	0.50	1.00	1.00	1.00
	206	Imipramine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	3.00
	207	Imipramine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	6.00	6.00	5.00	5.00
				Efficacy index (*)		2.00	2.00	3.00	1.50	3.00	3.00

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2
1

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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28

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/05	208	Reboxetine	Male	Severity of illness	5.00	4.00	4.00	3.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	2.00	2.00	1.00	1.00
				Efficacy index		9.00	5.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	4.00	4.00
	209	Placebo	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	14.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	0.50	1.00	1.00
	210	Reboxetine	Male	Severity of illness	5.00	4.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		9.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	4.00	4.00	4.00	4.00
	541	Reboxetine	Female	Severity of illness	5.00	3.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		5.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	3.00	4.00	4.00	4.00	4.00
	542	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		14.00	9.00	9.00	9.00	5.00	5.00
				Efficacy index (*)		6.50	2.00	2.00	3.00	3.00	3.00
	543	Imipramine	Male	Severity of illness	4.00	3.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index		9.00	6.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	1.50	3.00	4.00	4.00	4.00
	544	Placebo	Female	Severity of illness	5.00	5.00	5.00	6.00	6.00	6.00	6.00
				Global improvement		4.00	4.00	5.00	5.00	5.00	5.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.00
	545	Placebo	Male	Severity of illness	6.00	6.00	6.00	6.00	6.00	6.00	6.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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29

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0
CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
7/05	546	Reboxetine	Female	Severity of illness	5.00	4.00	3.00	3.00	3.00	3.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	4.00
7/07	529	Placebo	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	3.00	4.00	3.00	3.00
				Efficacy index		13.00	11.00	8.00	15.00	6.00	10.00
				Efficacy index (*)		1.00	0.67	0.75	0.33	1.50	1.00
530	Imipramine	Female	Severity of illness	5.00	4.00	5.00					
			Global improvement		4.00	3.00					
			Efficacy index		16.00	12.00					
				Efficacy index (*)		0.25	0.50				
531	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	4.00	3.00	4.00
			Global improvement		4.00	3.00	2.00	2.00	2.00	3.00	
			Efficacy index		13.00	9.00	5.00	5.00	5.00	3.00	
				Efficacy index (*)		1.00	2.00	3.00	3.00	3.00	3.00
532	Imipramine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00	3.00	3.00	3.00
			Global improvement		4.00	3.00	3.00	3.00	3.00	1.00	
			Efficacy index		9.00	9.00	9.00	9.00	9.00	5.00	
				Efficacy index (*)		2.00	2.00	2.00	2.00	2.00	3.00
533	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	4.00	3.00
			Global improvement		4.00	4.00	4.00	4.00	3.00	2.00	
			Efficacy index		14.00	14.00	13.00	9.00	9.00	5.00	
				Efficacy index (*)		0.50	0.50	1.00	2.00	2.00	3.00
534	Placebo	Female	Severity of illness	5.00	5.00	4.00	4.00	5.00	4.00	3.00	3.00
			Global improvement		4.00	3.00	3.00	3.00	3.00	2.00	
			Efficacy index		13.00	9.00	9.00	9.00	9.00	5.00	
				Efficacy index (*)		1.00	2.00	2.00	2.00	2.00	3.00
8	211	Reboxetine	Female	Severity of illness	4.00	4.00	5.00				
				Global improvement		4.00	6.00				
				Efficacy index		13.00	13.00				
				Efficacy index (*)		1.00	1.00				

1523

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=mainly worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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30

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	212	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	3.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	9.00	13.00	13.00	13.00
				Efficacy index (*)	1.00	1.00	2.00	1.00	1.00	1.00	
	213	Imipramine	Male	Severity of illness	4.00						
				Global improvement							
				Efficacy index							
				Efficacy index (*)							
	214	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.00	
	215	Placebo	Female	Severity of illness	3.00	2.00	2.00	2.00	2.00	1.00	1.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		5.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)	3.00	3.00	4.00	4.00	4.00	4.00	
	216	Imipramine	Male	Severity of illness	3.00	3.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	3.00
				Efficacy index		13.00	13.00	9.00	9.00	9.00	9.00
				Efficacy index (*)	1.00	1.00	2.00	2.00	2.00	2.00	
	217	Reboxetine	Female	Severity of illness	3.00	3.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index (*)	2.00	3.00	3.00	3.00	3.00	3.00	
	218	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		13.00	9.00	9.00	9.00	5.00	5.00
				Efficacy index (*)	1.00	2.00	2.00	2.00	3.00	3.00	
	219	Placebo	Female	Severity of illness	3.00	3.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	9.00	9.00	5.00	5.00
				Efficacy index (*)	2.00	2.00	2.00	2.00	3.00	3.00	

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1524

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=moderately ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=such worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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31

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	220	Imipramine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	4.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	13.00	5.00	5.00	5.00	5.00
				Efficacy index (*)	1.00	1.00	3.00	3.00	3.00	3.00	
	221	Imipramine	Male	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	2.00
				Global improvement		4.00	4.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	13.00	5.00	5.00	5.00	5.00
				Efficacy index (*)	1.00	1.00	3.00	3.00	3.00	3.00	
	222	Placebo	Female	Severity of illness	3.00	3.00	3.00	2.00	1.00	2.00	2.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		5.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)	3.00	3.00	4.00	4.00	4.00	4.00	
11	223	Imipramine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		13.00	9.00	9.00	9.00	5.00	5.00
				Efficacy index (*)	1.00	2.00	2.00	2.00	2.00	3.00	
20	224	Placebo	Female	Severity of illness	4.00	4.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	9.00	9.00	5.00	5.00
				Efficacy index (*)	2.00	2.00	2.00	2.00	3.00	3.00	
51	225	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	4.00	4.00	3.00	3.00	2.00
				Efficacy index		13.00	13.00	13.00	9.00	9.00	5.00
				Efficacy index (*)	1.00	1.00	1.00	2.00	2.00	3.00	
	226	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.00	
	227	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		13.00	9.00	9.00	9.00	9.00	9.00
				Efficacy index (*)	1.00	2.00	2.00	2.00	2.00	2.00	

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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32

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	228	Imipramine	Male	Severity of illness	4.00	4.00					
				Global improvement		5.00					
				Efficacy index	13.00	13.00					
				Efficacy index (*)	1.00	1.00					
	229	Imipramine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00	4.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	2.00
				Efficacy index	13.00	13.00	9.00	9.00	9.00	9.00	5.00
				Efficacy index (*)	1.00	2.00	2.00	2.00	2.00	3.00	
	230	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	3.00
				Efficacy index	13.00	13.00	13.00	9.00	9.00	9.00	9.00
				Efficacy index (*)	1.00	1.00	1.00	2.00	2.00	2.00	
10	231	Imipramine	Male	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index	13.00	13.00	9.00	9.00	9.00	9.00	5.00
				Efficacy index (*)	1.00	2.00	3.00	3.00	3.00	3.00	
10	232	Reboxetine	Male	Severity of illness	4.00	4.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	2.00
				Efficacy index	13.00	13.00	9.00	9.00	9.00	9.00	5.00
				Efficacy index (*)	1.00	2.00	2.00	2.00	3.00	3.00	
10	233	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	4.00	4.00	4.00	3.00	2.00
				Efficacy index	13.00	13.00	13.00	13.00	9.00	9.00	5.00
				Efficacy index (*)	1.00	1.00	1.00	1.00	2.00	3.00	
8/A	235	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index	13.00	13.00	13.00	9.00	9.00	9.00	9.00
				Efficacy index (*)	1.00	1.00	1.00	2.00	2.00	2.00	
				Severity of illness	5.00	5.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index	9.00	9.00	9.00	9.00	9.00	9.00	9.00
				Efficacy index (*)	2.00	2.00	2.00	2.00	2.00	2.00	2.00

9550082

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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9550082

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8/A	236	Placebo	Female	Severity of illness	5.00	5.00	3.00	3.00	3.00	2.00	2.00
				Global improvement	3.00	3.00	2.00	2.00	2.00	2.00	
				Efficacy index	9.00	5.00	5.00	5.00	5.00	5.00	
				Efficacy index (*)	2.00	3.00	3.00	3.00	3.00	3.00	
	237	Reboxetine	Female	Severity of illness	6.00	5.00	4.00	3.00	3.00	2.00	2.00
				Global improvement	3.00	3.00	2.00	2.00	2.00	2.00	
				Efficacy index	10.00	9.00	9.00	5.00	5.00	5.00	
				Efficacy index (*)	1.00	2.00	3.00	3.00	3.00	3.00	
	238	Reboxetine	Female	Severity of illness	5.00	4.00	3.00	3.00	2.00	2.00	2.00
				Global improvement	3.00	2.00	2.00	2.00	2.00	2.00	
				Efficacy index	9.00	5.00	5.00	5.00	5.00	5.00	
				Efficacy index (*)	2.00	3.00	3.00	3.00	3.00	3.00	
152	239	Imipramine	Female	Severity of illness	5.00	4.00	4.00	3.00	2.00	3.00	3.00
				Global improvement	3.00	3.00	3.00	3.00	2.00	2.00	
				Efficacy index	9.00	5.00	5.00	9.00	5.00	6.00	
				Efficacy index (*)	2.00	3.00	2.00	3.00	1.50	3.00	
27	240	Imipramine	Female	Severity of illness	6.00	5.00	5.00	4.00	3.00	3.00	3.00
				Global improvement	4.00	3.00	3.00	3.00	3.00	3.00	
				Efficacy index	13.00	9.00	9.00	9.00	9.00	9.00	
				Efficacy index (*)	1.00	2.00	2.00	2.00	2.00	2.00	
553	553	Placebo	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	4.00	3.00
				Global improvement	4.00	3.00	3.00	3.00	3.00	3.00	
				Efficacy index	13.00	9.00	9.00	9.00	9.00	9.00	
				Efficacy index (*)	1.00	2.00	2.00	2.00	2.00	2.00	
554	554	Reboxetine	Male	Severity of illness	5.00	5.00	4.00	3.00	2.00	2.00	2.00
				Global improvement	3.00	3.00	2.00	2.00	2.00	1.00	
				Efficacy index	9.00	9.00	9.00	5.00	5.00	1.00	
				Efficacy index (*)	2.00	2.00	3.00	3.00	3.00	4.00	
555	555	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	3.00	4.00	2.00
				Global improvement	3.00	3.00	3.00	3.00	3.00	2.00	
				Efficacy index	10.00	9.00	9.00	9.00	9.00	5.00	
				Efficacy index (*)	1.00	2.00	2.00	2.00	3.00	3.00	

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

34

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015

Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8/4	556	Imipramine	Male	Severity of illness	5.00	5.00	4.00	3.00	2.00	2.00	2.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	1.00
				Efficacy index		13.00	9.00	5.00	5.00	5.00	1.00
				Efficacy index (*)		1.00	2.00	3.00	3.00	3.00	4.00
9	241	Placebo	Female	Severity of illness	5.00	5.00	6.00				
				Global improvement		5.00	6.00				
				Efficacy index		14.00	15.00				
				Efficacy index (*)		0.50	0.33				
	242	Reboxetine	Female	Severity of illness	5.00	4.00	5.00	5.00			
				Global improvement		3.00	4.00	4.00			
				Efficacy index		10.00	14.00	15.00			
				Efficacy index (*)		1.00	0.50	0.33			
	243	Reboxetine	Female	Severity of illness	4.00	4.00	5.00				
				Global improvement		5.00	6.00				
				Efficacy index		14.00	15.00				
				Efficacy index (*)		0.50	0.33				
	244	Imipramine	Female	Severity of illness	5.00	4.00	4.00	4.00			
				Global improvement		3.00	3.00	3.00			
				Efficacy index		10.00	10.00	10.00			
				Efficacy index (*)		1.00	1.00	1.00			
	245	Imipramine	Female	Severity of illness	4.00	4.00	3.00	2.00	1.00	1.00	1.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		13.00	5.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	3.00	2.00	2.00	2.00	2.00
	246	Placebo	Female	Severity of illness	6.00	6.00	6.00	6.00	6.00		
				Global improvement		4.00	4.00	4.00	4.00		
				Efficacy index		13.00	13.00	13.00	16.00		
				Efficacy index (*)		1.00	1.00	1.00	0.25		
	247	Placebo	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00		
				Global improvement		4.00	3.00	4.00	4.00		
				Efficacy index		13.00	9.00	14.00	14.00		
				Efficacy index (*)		1.00	2.00	0.50	0.50		

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill, 8=very severely ill
 GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=moderately improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
 EFFICACY INDEX (*): computed from the vector activity by the vector side effects

157
28

9550082

35

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	248	Placebo	Male	Severity of illness	5.00	5.00	6.00				
				Global improvement		5.00	6.00				
				Efficacy index		13.00	15.00				
				Efficacy index (*)		1.00	0.33				
	249	Reboxetine	Female	Severity of illness	4.00						
				Global improvement							
				Efficacy index							
				Efficacy index (*)							
	250	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00		
				Global improvement		4.00	4.00	4.00	4.00		
				Efficacy index		13.00	13.00	14.00	13.00		
				Efficacy index (*)		1.00	1.00	0.50	1.00		
	251	Imipramine	Female	Severity of illness	5.00	4.00	5.00	2.00	1.00		
				Global improvement		2.00	4.00	1.00	1.00		
				Efficacy index		6.00	10.00	2.00	2.00		
				Efficacy index (*)		1.50	1.00	2.00	2.00		
	252	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00			
				Global improvement		5.00	4.00	5.00			
				Efficacy index		14.00	15.00	16.00			
				Efficacy index (*)		0.50	0.33	0.25			
	253	Reboxetine	Female	Severity of illness	5.00	6.00					
				Global improvement		6.00					
				Efficacy index		15.00					
				Efficacy index (*)		0.33					
	254	Imipramine	Female	Severity of illness	5.00	5.00	5.00				
				Global improvement		5.00	5.00				
				Efficacy index		15.00	15.00				
				Efficacy index (*)		0.33	0.33				
	255	Reboxetine	Female	Severity of illness	5.00	5.00	6.00	5.00	5.00		
				Global improvement		4.00	5.00	6.00			
				Efficacy index		15.00	14.00	15.00			
				Efficacy index (*)		1.00	0.50	0.50	0.33		

1529

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

36

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	256	Imipramine	Female	Severity of illness	6.00	6.00	4.00	4.00	5.00	4.00	4.00
				Global improvement		4.00	2.00	2.00	3.00	3.00	3.00
				Efficacy index	14.00	7.00	7.00	11.00	6.00	6.00	
				Efficacy index (*)	0.50	1.00	1.50	0.67	1.50	1.50	
257	257	Placebo	Male	Severity of illness	4.00	4.00					
				Global improvement		4.00					
				Efficacy index	13.00						
				Efficacy index (*)	1.00						
258	258	Placebo	Male	Severity of illness	4.00	4.00	4.00				
				Global improvement		4.00	4.00				
				Efficacy index	14.00	14.00					
				Efficacy index (*)	0.50	0.50					
11	319	Placebo	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	4.00
				Global improvement		4.00	4.00	5.00	4.00	4.00	4.00
				Efficacy index	13.00	13.00	13.00	13.00	13.00	13.00	
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.00	
320	320	Imipramine	Male	Severity of illness	5.00	5.00	3.00	5.00	3.00	4.00	3.00
				Global improvement		5.00	2.00	5.00	2.00	3.00	2.00
				Efficacy index	14.00	6.00	14.00	6.00	10.00	6.00	
				Efficacy index (*)	0.50	1.50	0.50	1.50	1.00	1.50	
321	321	Placebo	Male	Severity of illness	4.00	4.00	4.00	3.00	2.00	1.00	1.00
				Global improvement		4.00	3.00	2.00	1.00	1.00	1.00
				Efficacy index	13.00	10.00	10.00	6.00	2.00	2.00	2.00
				Efficacy index (*)	1.00	1.00	1.50	2.00	2.00	2.00	
322	322	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		3.00	3.00	3.00	3.00	4.00	4.00
				Efficacy index	10.00	10.00	10.00	10.00	14.00	14.00	
				Efficacy index (*)	1.00	1.00	1.00	1.00	0.50	0.50	
323	323	Reboxetine	Male	Severity of illness	4.00	4.00	3.00	2.00	1.00	1.00	1.00
				Global improvement		3.00	2.00	4.00	1.00	1.00	1.00
				Efficacy index	10.00	6.00	2.00	2.00	2.00	1.00	1.00
				Efficacy index (*)	1.00	1.50	2.00	2.00	4.00	4.00	

1530

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

37

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	324	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	3.00	4.00	4.00	4.00
				Efficacy index	13.00	10.00	10.00	14.00	14.00	14.00	
				Efficacy index (*)	1.00	1.00	1.00	0.50	0.50	0.50	
	325	Reboxetine	Male	Severity of illness	4.00	3.00	3.00	1.00	1.00	1.00	1.00
				Global improvement		2.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index	5.00	5.00	1.00	1.00	1.00	1.00	
				Efficacy index (*)	3.00	3.00	4.00	4.00	4.00	4.00	
	326	Placebo	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		5.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index	13.00	13.00	13.00	13.00	13.00	13.00	
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.00	
	327	Imipramine	Male	Severity of illness	4.00	3.00					
				Global improvement		2.00					
				Efficacy index	6.00	6.00					
				Efficacy index (*)	1.50						
	328	Imipramine	Female	Severity of illness	4.00	4.00					
				Global improvement		3.00					
				Efficacy index	11.00	11.00					
				Efficacy index (*)	0.67						
	329	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	2.00	2.00	2.00
				Global improvement		4.00	4.00	4.00	1.00	1.00	1.00
				Efficacy index	14.00	14.00	13.00	13.00	1.00	1.00	
				Efficacy index (*)	0.50	1.00	1.00	4.00	4.00	4.00	
	330	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	2.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index	14.00	10.00	9.00	5.00	5.00	1.00	
				Efficacy index (*)	0.50	1.00	2.00	3.00	3.00	4.00	
	331	Imipramine	Male	Severity of illness	4.00	4.00	3.00	2.00	3.00	3.00	3.00
				Global improvement		3.00	2.00	1.00	2.00	2.00	3.00
				Efficacy index	10.00	6.00	2.00	6.00	6.00	6.00	
				Efficacy index (*)	1.00	1.50	2.00	1.50	1.50	1.50	

1531

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

38

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
11	332	Reboxetine	Male	Severity of illness	4.00	4.00	3.00	2.00	1.00	2.00	2.00	
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00	
				Efficacy index		5.00	5.00	1.00	1.00	1.00	1.00	
					Efficacy index (*)	3.00	3.00	4.00	4.00	4.00	4.00	
	333	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	4.00	2.00	2.00	2.00	2.00	
				Efficacy index		14.00	13.00	5.00	6.00	6.00	5.00	
					Efficacy index (*)	0.50	1.00	3.00	1.50	1.50	3.00	
	334	Reboxetine	Female	Severity of illness	4.00							
				Global improvement		16.00						
				Efficacy index		0.25						
					Efficacy index (*)							
335	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	
			Global improvement		3.00	3.00	3.00	3.00	3.00	3.00		
			Efficacy index		9.00	9.00	9.00	9.00	9.00	9.00		
				Efficacy index (*)	2.00	2.00	2.00	2.00	2.00	2.00		
336	Imipramine	Female	Severity of illness	5.00	5.00							
			Global improvement		4.00							
			Efficacy index		13.00							
				Efficacy index (*)	1.00							
337	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	
			Global improvement		4.00	4.00	4.00	4.00	4.00	4.00		
			Efficacy index		14.00	14.00	14.00	13.00	13.00	13.00		
				Efficacy index (*)	0.50	0.50	1.00	1.00	1.00	1.00		
338	Imipramine	Male	Severity of illness	5.00	4.00							
			Global improvement		3.00							
			Efficacy index		9.00							
				Efficacy index (*)	2.00							
12	367	Reboxetine	Female	Severity of illness	5.00	3.00	3.00	1.00	1.00	1.00	2.00	
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00	
				Efficacy index		10.00	6.00	2.00	2.00	2.00	2.00	
				Efficacy index (*)	1.00	1.50	2.00	2.00	2.00	2.00		

1533

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

9550082

39

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
12	368	Placebo	Female	Severity of illness	4.00	4.00	4.00	3.00	2.00	2.00	2.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	2.00
				Efficacy index		13.00	14.00	10.00	9.00	9.00	5.00
				Efficacy index (*)	1.00	0.50	1.00	2.00	2.00	3.00	
	369	Imipramine	Female	Severity of illness	5.00	1.00	2.00	6.00			
				Global improvement		1.00	3.00	7.00			
				Efficacy index		2.00	10.00	13.00			
				Efficacy index (*)	2.00	1.00	1.00				
	370	Placebo	Male	Severity of illness	5.00	4.00	5.00	5.00	5.00		
				Global improvement		3.00	3.00	6.00	6.00		
				Efficacy index		10.00	9.00	14.00	13.00		
				Efficacy index (*)	1.00	2.00	0.50	1.00			
	371	Imipramine	Female	Severity of illness	4.00	2.00					
				Global improvement		2.00					
				Efficacy index		6.00					
				Efficacy index (*)	1.50						
	372	Reboxetine	Male	Severity of illness	5.00	5.00	3.00	2.00	2.00	1.00	3.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	2.00
				Efficacy index		10.00	2.00	2.00	2.00	2.00	6.00
				Efficacy index (*)	1.00	2.00	2.00	2.00	2.00	1.50	
	373	Reboxetine	Male	Severity of illness	6.00	2.00	5.00	4.00	4.00	2.00	1.00
				Global improvement		1.00	4.00	2.00	3.00	2.00	1.00
				Efficacy index		2.00	14.00	2.00	10.00	2.00	2.00
				Efficacy index (*)	2.00	0.50	2.00	1.00	2.00	2.00	
	374	Placebo	Female	Severity of illness	5.00	4.00	3.00	4.00	4.00	2.00	2.00
				Global improvement		3.00	3.00	5.00	3.00	3.00	1.00
				Efficacy index		10.00	9.00	13.00	9.00	9.00	2.00
				Efficacy index (*)	1.00	2.00	1.00	1.00	2.00	2.00	
	375	Imipramine	Male	Severity of illness	5.00						
				Global improvement							
				Efficacy index							
				Efficacy index (*)							

1533

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

40

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	13	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		3.00	3.00	5.00	4.00	4.00	4.00
				Efficacy index		10.00	10.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.00
14	14	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	3.00	4.00	4.00
				Global improvement		3.00	5.00	4.00	2.00	3.00	3.00
				Efficacy index		6.00	14.00	14.00	6.00	10.00	10.00
				Efficacy index (*)		1.50	0.50	1.50	1.00	1.00	
15	15	Imipramine	Female	Severity of illness	5.00	4.00	3.00	4.00	4.00	4.00	4.00
				Global improvement		3.00	3.00	3.00	5.00	4.00	5.00
				Efficacy index		10.00	10.00	10.00	14.00	14.00	14.00
				Efficacy index (*)		1.00	1.00	1.00	0.50	0.50	
16	16	Imipramine	Male	Severity of illness	4.00	4.00	4.00	3.00	4.00	3.00	4.00
				Global improvement		5.00	5.00	2.00	5.00	3.00	6.00
				Efficacy index		14.00	14.00	6.00	13.00	10.00	14.00
				Efficacy index (*)		0.50	0.50	1.50	1.00	1.00	
17	17	Reboxetine	Male	Severity of illness	4.00	4.00	3.00	4.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	4.00	3.00	3.00	3.00
				Efficacy index		14.00	10.00	10.00	10.00	10.00	10.00
				Efficacy index (*)		0.50	1.00	1.00	1.00	1.00	
18	18	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	3.00	4.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	5.00	3.00	3.00
				Efficacy index		10.00	10.00	9.00	14.00	10.00	10.00
				Efficacy index (*)		1.00	1.00	2.00	0.50	1.00	
409	409	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	3.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	3.00
				Efficacy index		14.00	14.00	14.00	14.00	14.00	10.00
				Efficacy index (*)		0.50	0.50	0.50	0.50	1.00	
410	410	Placebo	Male	Severity of illness	5.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		5.00	4.00	4.00	3.00	4.00	3.00
				Efficacy index		14.00	14.00	14.00	10.00	14.00	10.00
				Efficacy index (*)		0.50	0.50	1.00	0.50	1.00	

1 3 3 4

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

41

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	411	Imipramine	Female	Severity of illness	5.00	4.00	3.00	4.00	4.00	4.00	4.00
				Global improvement		3.00	2.00	5.00	6.00	4.00	3.00
				Efficacy index		10.00	6.00	14.00	14.00	14.00	10.00
				Efficacy index (*)		1.00	1.50	0.50	0.50	1.00	
14	423	Placebo	Male	Severity of illness	3.00	3.00	4.00	4.00			3.00
				Global improvement		4.00	4.00	4.00			2.00
				Efficacy index		13.00	13.00	13.00			5.00
				Efficacy index (*)		1.00	1.00	1.00		3.00	
14	19	Reboxetine	Female	Severity of illness	6.00	6.00	5.00	5.00	6.00		6.00
				Global improvement		5.00	3.00	4.00	4.00		4.00
				Efficacy index		13.00	10.00	14.00	13.00		13.00
				Efficacy index (*)		1.00	1.00	0.50	1.00	1.00	
15	20	Imipramine	Female	Severity of illness	5.00	5.00	4.00	3.00	2.00	1.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	1.00	1.00
				Efficacy index		14.00	11.00	7.00	3.00	3.00	2.00
				Efficacy index (*)		0.50	0.67	1.00	1.33	1.33	
15	21	Imipramine	Female	Severity of illness	5.00	5.00	4.00	5.00	4.00	4.00	4.00
				Global improvement		3.00	3.00	4.00	3.00	4.00	4.00
				Efficacy index		10.00	10.00	14.00	10.00	14.00	14.00
				Efficacy index (*)		1.00	1.00	0.50	1.00	0.50	
15	25	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	4.00	3.00	5.00	5.00
				Efficacy index		14.00	10.00	10.00	10.00	14.00	14.00
				Efficacy index (*)		0.50	1.00	1.00	1.00	0.50	
15	26	Placebo	Male	Severity of illness	4.00	4.00	3.00	3.00	4.00	3.00	2.00
				Global improvement		3.00	2.00	6.00	6.00	2.00	2.00
				Efficacy index		10.00	6.00	6.00	14.00	6.00	6.00
				Efficacy index (*)		1.00	1.50	1.50	0.50	1.50	
15	27	Imipramine	Female	Severity of illness	4.00	4.00	4.00	2.00	2.00	2.00	1.00
				Global improvement		3.00	3.00	2.00	1.00	1.00	1.00
				Efficacy index		10.00	10.00	6.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.00	1.50	2.00	2.00	

1535

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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42

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	28	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 14.00 0.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	2.00 2.00 6.00 1.50	2.00 2.00 6.00 1.50	1.00 1.00 2.00 2.00
29		Placebo	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 13.00 1.00	4.00 3.00 10.00 1.00	4.00 4.00 14.00 0.50	4.00 3.00 14.00 0.50	4.00 3.00 14.00 0.50	4.00 3.00 14.00 0.50
30		Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00
403		Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	2.00 1.00 2.00 2.00
404		Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 13.00 1.00	4.00 4.00 14.00 0.50	4.00 4.00 14.00 0.50	4.00 4.00 14.00 0.50	4.00 4.00 14.00 0.50	4.00 4.00 14.00 0.50
405		Placebo	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	2.00 1.00 5.00 3.00
406		Imipramine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 14.00 0.50	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	3.00 2.00 5.00 3.00
407		Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	4.00 3.00 10.00 1.00	3.00 2.00 6.00 0.75

1536

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SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3= mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

43

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	408	Placebo	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	4.00	2.00	2.00	2.00	2.00
				Efficacy index	13.00	14.00	6.00	5.00	6.00	6.00	
				Efficacy index (*)	1.00	0.50	1.50	3.00	1.50	1.50	
	418	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	1.00
				Global improvement		4.00	4.00	3.00	3.00	2.00	1.00
				Efficacy index	14.00	14.00	9.00	9.00	6.00	2.00	
				Efficacy index (*)	0.50	0.50	2.00	2.00	1.50	2.00	
	419	Placebo	Female	Severity of illness	4.00	3.00	4.00	4.00	3.00	3.00	3.00
				Global improvement		2.00	4.00	4.00	2.00	2.00	2.00
				Efficacy index	6.00	14.00	14.00	6.00	6.00	6.00	
				Efficacy index (*)	1.50	0.50	0.50	1.50	1.50	1.50	

1537

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

9550082

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PHARMACIA CMS RED

REDBOXIME - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End No date	Last report visit	Sev	Hist	R1	Stud	Somp	Dis	Re	Out	Skill	
			Start date	End date															
1	1	Emipramine	18/04/91	22/05/91	CONFUSION				17/04/91(18)	Summary	16								YES
					CONSTIPATION				24/06/91(18)	Summary	21								YES
					DYSPEPSIA				17/04/91	Detail	21								
									02/11/05/91	Detail	42	3	2	5	1	YES	2	3	3
									11/05/91	Summary	42	3	2	2	1	YES	2	3	1
																			YES
					INSOMNIA				24/04/91(18)	Detail	21								YES
									01/05/91(*)	Summary	21								YES
					MOUTH DRY					Detail	7								
										Detail	14								
										Detail	21								
									10/04/91(18)	Summary	21								YES
					NAUSEA				10/04/91(18)	Detail	7								YES
									17/04/91(*)	Summary	7								YES
					PARAESTHESIA					Detail	7								
										Detail	28								
										Detail	35								
									10/04/91(18)	Summary	35								YES
					SWEATING INCREASED				10/04/91(18)	Detail	7								YES
									17/04/91(*)	Summary	7								YES
					TACHYCARDIA					Detail	21								
										Detail	28								
									24/04/91(18)	Summary	28								YES

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=critical
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=none, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; end date a visit date
 (**) onset date missing; first report visit date used

1538

9550082

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PHARMACIA CNS RED
 REBOETINE - PROTOCOL 20124/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit End No date	Last report visit	Sv	Hst	Mst	Rel	Stu	Dis	Re	Out	Skill
			Start date	End date													
1	1	Imipramine	17/04/91	22/05/91	VISION ABNORMAL	Detail	21	2	2	5	1	2	5	1	3		
						Detail	35	2	2	1	2	5	3				
						Summary	22/05/91(*)	35	2	2	1	2	3	3	Y	YES	
						Detail	7	1	2	3	1	5	3	3			
						Summary	22/04/91(*)	7	1	2	3	1	5	3	3	Y	YES
						Detail	7	1	2	3	1	5	3	3			
						Detail	42	2	3	1	5	3	3	3	Y		
						Summary	27/05/91(*)	42	1	2	3	1	5	3	3	Y	YES
						Detail	7	1	2	3	1	5	3	3			
						Summary	22/04/91(*)	7	1	2	3	1	5	3	3	Y	YES
2	2	Reboetine	15/04/91	27/05/91	ASTIGMIA	Detail	7	1	2	3	1	5	3	3			
						Summary	22/04/91(*)	7	1	2	3	1	5	3	3	Y	YES
						Detail	7	1	2	3	1	5	3	3			
						Detail	42	2	3	1	5	3	3	3	Y		
						Summary	27/05/91(*)	42	1	2	3	1	5	3	3	Y	YES
						Detail	7	1	2	3	1	5	3	3			
						Detail	14	2	3	1	5	3	3	3	Y		
						Summary	30/04/91(*)	14	1	2	3	1	2	3	3	Y	YES
						Detail	7	1	2	3	1	5	3	3			
						Summary	30/04/91(*)	7	1	2	3	1	5	3	3	Y	YES
3	3	Reboetine	14/05/91	20/05/91	ASTIGMIA	Detail	85	1	2	3	1	2	3	3			
						Summary	20/05/91(*)	85	1	2	3	1	2	3	3	Y	YES
						Detail	14	2	3	1	5	3	3	3			
						Summary	30/04/91(*)	14	1	2	3	1	5	3	3	Y	YES
						Detail	14	2	3	1	5	3	3	3			
						Summary	30/04/91(*)	14	1	2	3	1	5	3	3	Y	YES
						Detail	14	2	3	1	5	3	3	3			
						Summary	30/04/91(*)	14	1	2	3	1	5	3	3	Y	YES
						Detail	14	2	3	1	5	3	3	3			
						Summary	06/05/91(*)	21	2	4	1	3	3	3	Y	YES	
4	4	Reboetine	22/04/91	22/04/91	MOUTH DRY	Detail	7	1	2	3	1	2	3	3			
						Detail	35	1	1	5	1	2	5	3			
						Detail	42	1	1	5	1	3	3	3	Y		
						Summary	27/05/91(*)	42	1	1	5	1	2	3	3	Y	YES
						Detail	7	1	2	3	1	5	3	3			
						Detail	35	1	1	5	1	2	5	3			
						Detail	42	1	1	5	1	3	3	3	Y		
						Summary	27/05/91(*)	42	1	1	5	1	2	3	3	Y	YES
						Detail	7	1	2	3	1	5	3	3			
						Summary	22/04/91(*)	7	1	2	3	1	5	3	3	Y	YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (O) onset date missing: first report visit date used

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment		Onset date	Adverse event	Dose/dt	Type record	Visit No	End date	Last report visit	Sae	Hist ary	Rai	Stud	Symp	Dis app.	Re Hospt.	Out app.	Still some present (C)	
		Start date	End date																	
1	2	Reboxetine	15/04/91	27/05/91	NERVOUSNESS	22/04/91	Detail	7		7	1	2	3	1	3	3	3	3	3	YES
			Summary	22/04/91(*)				7	1	2	3	1	3	3	3	3	3			
			Summary	22/04/91(*)				7	1	2	3	1	3	3	3	3	3			
3	3	ImDramine	30/04/91	15/06/91	VISION ABNORMAL	30/04/91	Detail	14		14	2	1	1	1	1	1	1	1	1	YES
			Detail	26				13/05/91(*)	26	2	1	1	1	1	1	1	1			
			Summary	13/05/91(*)				26	2	1	1	1	1	1	1	1	1			
4	4	Placebo	15/05/91	16/07/91	MOUTH DRY	15/05/91	Detail	35		35	1	1	1	1	1	1	1	1	1	YES
			Detail	28				21/05/91	28	3	2	1	2	2	1	2	2	1		
			Summary	17/06/91(*)				42	3	2	2	1	2	2	1	2	2	1		
4	4	Placebo	16/07/91	16/07/91	FATIGUE	12/06/91	Detail	14		14	2	2	4	1	2	2	3	3	3	YES
			Detail	14				15/06/91(*)	14	2	2	4	1	2	2	3	3	3		
			Summary	11/06/91(*)				7	1	2	3	1	3	3	3	3	3			
5	5	Reboxetine	12/06/91	02/07/91	MOUTH DRY	12/06/91	Detail	21		21	1	2	4	1	2	2	3	3	3	YES
			Detail	21				25/06/91(*)	21	1	2	4	1	2	2	3	3	3		
			Summary	25/06/91(*)				21	1	2	4	1	2	2	3	3	3			

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
 Study drug: 1= no change, 2= dose reduced, 3= def. withdrawn, 4= temp. inter.
 Hospital: 1= required, 2= not req., 3= not appl. -- Outcome: 1= recovered, 2= rec. with seq., 3= still present, 4= death
 Disapp./Reapp.: 1= no, 2= yes, 3= not appl. -- Relationship: 1= definite, 2= probable, 3= possible, 4= doubtful, 5= unknown, 6= none
 symptomatic treatment: 0= no, 1= yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (D) onset date missing; first report visit date used

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4

PHARMACIA CAS RED
 REBOMETINE - PROTOCOL 2012/015
 Listing No.: 17.9
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Saw rfty	Hist ory	Rel ship	Rat	Stud Sym	Dis app.	Re come	Out	Still
1	5	Rebometine	12/06/91	02/07/91	SWEATING INCREASED	16/06/91	Detail	7		16/06/91	1	2	3	1	2	3	3	3	3
							Summary	14		25/05/91(*)	14	1	2	3	1	2	3	3	3
					TOOTH DISORDER	12/06/91	Detail	14	19/06/91	14					YES				YES
							Summary		19/06/91						YES				YES
6	6	Placebo	25/05/91	05/07/91	ABDOMINAL PAIN	05/06/91	Detail	21		13/06/91(*)	21	2	1	3	1	5	3	3	3
							Summary								5	3	3	3	3
					ARTHRALGIA	25/05/91	Detail	7		30/05/91(*)	7	2	1	4	1	YES	2	3	3
							Summary								YES	2	3	3	3
					CONSTIPATION	30/05/91	Detail	14				2	2	2	1	3	3	3	3
							Detail	21				2	2	4	1	2	3	3	3
							Summary			05/07/91(*)	21	2	2	2	1	2	3	3	3
					FLATULENCE	30/05/91	Detail	21		05/07/91(*)	21	2	2	4	1	2	3	3	3
							Summary								2	3	3	3	3
					MICTURITION DISORDER	24/05/91	Detail	7		30/05/91(*)	7	2	1	1	1	3	3	3	3
							Summary								3	3	3	3	3
					MOUTH DRY	24/05/91	Detail	7				1	1	1	1	2	3	3	3
							Detail	14				1	1	3	1	3	3	3	3
							Detail	21				2	1	4	1	2	3	3	3
							Summary			05/07/91(*)	21	2	1	1	1	2	3	3	3
					NAUSEA	24/05/91	Detail	35		01/07/91(*)	35	2	2	3	1	3	3	3	3
							Summary								3	3	3	3	3
					PARONYCHIA	15/06/91	Detail	28				2	2	5	1	YES	3	3	3

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=requires, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (**) onset date missing: first report visit date used
 (c) onset date missing: first report visit date used

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5

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PHARMACIA, CNS R&D
 RESOMETINE - PROTOCOL 20154/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Save	Hist	Rel	Stud	Symp	Dis	Re	Out	Skill	Last report visit				
																				visit	ary	ship	drug	tree
1	6	Placebo	25/05/91	05/07/91	PARONYCHIA	16/06/91	Summary	28/06/91(*)	28	2	2	2	5	1	YES	3	3	3	3	3	YES			
			02/07/91		RASH	02/07/91	Detail	95/07/91	42	2	2	3	3	3	3	2	3	1	1	1	YES			
							Summary	95/07/91	42	2	2	3	3	3	3	2	3	1	1	1	YES			
			16/06/91		TASTE PERVERSION	16/06/91	Detail	28/06/91(*)	28	2	2	5	1	1	3	3	3	3	3	3	YES			
							Summary	28/06/91(*)	28	2	2	5	1	1	3	3	3	3	3	3	YES			
7		Reboxetine	27/06/91	08/10/91	DIZZINESS	28/08/91	Detail	28	28	2	2	5	1	1	2	3	3	3	3	3	YES			
							Detail	7	7	2	2	5	1	1	2	3	3	3	3	3	YES			
							Summary	28/08/91	28	2	2	5	1	1	2	3	3	3	3	3	YES			
			17/09/91(8)				Summary	28/08/91	28	28	2	2	5	1	2	3	3	3	3	3	YES			
			29/08/91		HEADACHE	29/08/91	Detail	7	7	2	2	5	1	1	3	3	3	3	3	3	YES			
							Summary	03/09/91(*)	7	2	2	5	1	1	3	3	3	3	3	3	YES			
			28/08/91		MOUTH DRY	28/08/91	Detail	7	7	1	2	5	1	1	2	3	3	3	3	3	YES			
							Summary	03/09/91(*)	7	1	2	5	1	1	2	3	3	3	3	3	YES			
			17/09/91(8)		SWEATING INCREASED	17/09/91(8)	Detail	28	28	28	2	2	5	1	2	3	3	3	3	3	YES			
							Summary	25/09/91(*)	28	28	28	2	2	5	1	2	3	3	3	3	YES			
			17/09/91(8)		VISION ABNORMAL	17/09/91(8)	Detail	28	28	28	2	2	5	1	2	3	3	3	3	3	YES			
							Summary	25/09/91(*)	28	28	28	2	2	5	1	2	3	3	3	3	YES			
8		Placebo	05/09/91	19/10/91	RHINITIS	20/09/91	Detail	21	21/09/91	21	1	2	5	1	1	YES	1	1	1	1	YES			
							Summary	21/09/91	21	21	1	2	5	1	1	YES	1	1	1	1	YES			
9		Reboxetine	27/11/91	06/01/92	HEADACHE	28/11/91	Detail	7	7	1	2	5	1	1	3	3	3	3	3	3	YES			
							Detail	35	35	1	2	3	1	1	3	3	3	3	3	3	YES			
							Summary	06/01/92(*)	35	1	2	3	1	1	3	3	3	3	3	3	YES			

-- History: 1=Present before, 2=not observe bef., 3=unknown
 Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (e) adverse event still present; end date = visit date
 (d) onset date missing; first report visit date used

1542

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PHARMACIA CNS RED
 REBOMETINE - PROTOCOL 2016/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last report visit	Sae Hist	Rel Ship	Stud Sympt	Dis app.	Re app.	Ont Still	
			Start date	End date												
1	9	Rebometine	27/11/91	06/01/92	27/11/91	Detail	7	86/11/92(*)	7	2	2	1	5	3	3	Y
			Summary													
10	Placebo	26/09/91	06/11/91	HEADACHE	26/09/91	Detail	20	86/11/91(*)	20	1	2	3	2	3	3	Y
			Summary													
11	Imipramine	10/10/91	13/10/91	DIZZINESS	11/10/91	Detail	7	14/10/91(*)	7	3	1	3	1	2	3	Y
			Summary													
12	Imipramine	16/10/91	30/11/91	DIZZINESS	26/10/91	Detail	14	81/11/91(*)	14	1	2	3	2	3	3	Y
			Summary													
12	Imipramine	16/10/91	05/11/91	HEADACHE	05/11/91	Detail	21	86/11/91(*)	21	2	2	4	2	3	3	Y
			Summary													
12	Imipramine	16/10/91	13/11/91	INFLUENZA-LIKE SYMPTOMS	13/11/91	Detail	20	15/11/91	20				YES			YES
			Summary												YES	
12	Imipramine	16/10/91	26/10/91	HEADACHE	26/10/91	Detail	14	81/11/91(*)	14	1	2	3	2	3	3	Y
			Summary													
12	Imipramine	16/10/91	05/11/91	HEADACHE	05/11/91	Detail	21	86/11/91(*)	21	2	2	4	2	3	3	Y
			Summary													
12	Imipramine	16/10/91	13/11/91	INFLUENZA-LIKE SYMPTOMS	13/11/91	Detail	20	15/11/91	20				YES			YES
			Summary												YES	
12	Imipramine	16/10/91	26/10/91	HEADACHE	26/10/91	Detail	14	81/11/91(*)	14	1	2	3	2	3	3	Y
			Summary													

Sae: 1=Unknown, 2=mild, 3=moderate, 4=severe, 5=life threatening, 6=death
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=requires, 2=not req., 3=not appl.
 Disapp./Reapp.: 1=yes, 2=yes, 3=not appl.
 Symptomatic treatment: 0=no, 1=yes
 (1) adverse event used for statistical analysis
 (2) adverse event still present; and date = visit date
 (3) onset date missing; first report visit date used
 (4) History: 1=present before, 2=not observe bef., 3=unknown

9550082

7

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PHARMACIA CNS RED
REBONETLINE - PROTOCOL 20124/015
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Save rcty	Hist drug	Re Hosp	Dis app.	Re code	Out	Still Present																																
																		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
1	12	Imipramine	18/10/91	30/11/91	PARAESTHESIA	18/10/91	Detail	7	25/10/91(*)	7	2	1	3	1	3	3	3	3																															
							Summary											YES																															
412	Rebonetline	18/11/91	23/12/91	CONSTIPATION	25/11/91	Detail	21	06/12/91(*)	21	3	2	4	1	3	3	3	3																																
							Summary											YES																															
413	Placebo	09/12/91	20/01/92	FATIGUE	05/12/91	Detail	28	09/12/91	28	1	2	4	1	2	3	3	1																																
							Summary											YES																															
413	Placebo	09/12/91	20/01/92	FATIGUE	17/12/91	Detail	21	20/01/92(*)	21	2	2	3	1	2	3	3	3																																
							Summary											YES																															
413	Placebo	23/12/91		HEADACHE	23/12/91	Detail	42	20/01/92(*)	42	1	3	3	1	2	3	3	3																																
							Summary											YES																															
413	Placebo	30/12/91		MOUTH DRY	30/12/91	Detail	21			1	2	4	1	2	3	3	3																																
							Summary											YES																															
415	Imipramine	14/01/92	27/02/92	COLD URTICARIA	25/01/92	Detail	14	28/01/92(*)	14	2	2	5	1	2	3	3	3																																
							Summary											YES																															
415	Imipramine	03/02/92		CONSTIPATION	03/02/92	Detail	21	27/02/92(*)	21	2	2	4	1	2	3	3	3																																
							Summary											YES																															
415	Imipramine	15/01/92		MOUTH DRY	15/01/92	Detail	7	27/02/92(*)	7	2	2	3	1	2	3	3	3																																
							Summary											YES																															
421	Imipramine	27/02/92	09/06/92	CONSTIPATION	06/03/92	Detail	14	09/06/92(*)	14	1	2	4	1	2	3	3	3																																
							Summary											YES																															

-- History: 1=Present before, 2=not observe bef., 5=unknown
Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=free. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(*) adverse event used for statistical analysis
(*) adverse event still present; end date = visit date
(*) onset date missing: first report visit date used

9550082

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PHARMACIA CNS RED
 REBOCETINE - PROTOCOL 20124/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Sav	Hist	Rel	Stud	Samp	Dis	Re	Out	Still								
																				visit	city	ory	ship	drug	tree	Hosp	app.
1	421	Imipramine	27/02/92	09/06/92	DIZZINESS	20/02/92	Detail	7					1	2	3	1	2	3	3	3							
							Detail	14																			
							Summary		12/05/92(*)				14	1	2	3	1	2	3	3						YES	
							Detail	42										2	2	3	1	2	3	3	3	3	Y
							Summary		09/06/92(*)				42	2	2	3	1	2	3	3	1	2	3	3	3	3	Y
							Detail	7										1	2	3	1	2	3	3	3	3	Y
							Summary		05/02/92(*)				7	1	2	3	1	2	3	3	1	2	3	3	3	3	Y
							Detail	7										2	2	3	1	3	3	3	3	3	Y
							Summary		09/06/92(*)				7	2	2	3	1	3	3	3	1	3	3	3	3	3	Y
							Detail	21										2	2	3	1	2	3	3	3	3	Y
							Summary		25/02/92				21	2	2	3	1	2	3	3	1	2	3	3	3	3	Y
							422	422	Imipramine	05/08/92	17/09/92	MOUTH DRY	05/08/92	Detail	14					1	2	3	1	2	3	3	3
Detail	14																										
Summary		17/09/92(*)				14								1	2	3	1	2	3	3	1	2	3	3	3	Y	
Detail	21																1	2	3	1	3	3	3	3	3	Y	
Summary		17/09/92(*)				21								1	2	3	1	3	3	3	1	3	3	3	3	3	Y

1545

Serious: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (D) onset date missing: first report visit date used

9550082

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PHARMACIA DNS RED
 REBOXETINE - PROTIDOL 20/26/91S
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Onset date	Type	Visit record	End date	Last report visit	Base	Hist	Rai	Stud	Symp	Dis	Re	Out	Still	Dis			
																				visit	city	ory	ship
2/1	49	Placebo	18/05/91	22/06/91	INSONNIA	15/05/91	0	0	0	0	3	3										NO	
							Summary		23/06/91(*)	0	3												
							Detail	7		1	2	3	1										
							Detail	14		1	2	3	1										
							Detail	21		1	2	3	1										
							Detail	28		1	2	3	1										
							Detail	35		1	2	3	1										
							Detail	42		1	2	3	1										
							Summary		25/05/91	42	1	2	3	1									YES
							Detail	7	21/05/91		2	2	3	1									YES
							Summary		21/05/91	7	2	2	3	1									YES
							Detail	7	21/05/91		3	2	3	1									YES
							Summary		21/05/91	7	3	2	3	1									YES
							Detail	28		2	2	3	1										
							Detail	35		1	2	3	1										
							Detail	42		2	2	3	1										Y
							Summary		06/02/92(*)	42	2	2	3	1									YES
							Detail	28	22/01/92		2	1	6	1	YES								
							Summary		22/01/92	28	2	1	6	1	YES								YES
							Detail	35	27/01/92		2	1	6	1	YES								
							Summary		27/01/92	35	2	1	6	1	YES								YES
							Detail	42	03/02/92		2	1	6	1	YES								YES
							Summary		03/02/92	42	2	1	6	1	YES								YES
							Detail	14															
							Detail	21	15/01/92		3	2	3	1									3
							Summary		15/01/92	21	3	2	3	1									3

1546

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life-threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (S) onset date missing: first report visit date used

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10

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

2/1	50	Reboxetine	27/12/91	06/02/92	GAMMA-GT INCREASED	Start date	End date	Treatment	Onset date	Type record	Visit No	Last report visit	Sae Hist	Rel. to study	Drug	Treat	Mosp	Dis app.	Re come	Out app.	Still present	C)	
																							Adverse event
						27/12/91	06/02/92		26/12/91	Detail	0	21	16/01/92	2	1	6	1	2	3	3	1		
										Summary	21	16/01/92	21	2	1	6	1	2	3	3	1		NO
					HEADACHE				31/12/91	Detail	7	31/12/91	1	3	6	1	YES	2	3	3	1		YES
										Summary	7	31/12/91	7	1	3	6	1	YES	2	3	3	1	
					HYPERTENSIA				29/12/91	Detail	7	29/12/91	1	3	6	1	YES	2	3	3	1		YES
										Summary	7	29/12/91	7	1	3	6	1	YES	2	3	3	1	
					INSOMNIA				22/12/91(0)	Detail	0	06/02/92(*)	0	3									NO
										Summary	0	06/02/92(*)	0	3									
					MOUTH DRY				29/12/91	Detail	7	29/12/91	2	2	3	1	2	3	3	3	3		
										Detail	14	29/12/91	2	2	3	1	2	3	3	3	3		
										Detail	21	29/12/91	2	2	3	1	2	3	3	3	3		
										Detail	28	29/12/91	2	2	3	1	2	3	3	3	3		
										Detail	35	29/12/91	2	2	3	1	2	3	3	3	3		
										Detail	42	29/12/91	2	2	3	1	2	3	3	3	3		
										Summary	06/02/92(*)	42	2	2	3	1	2	3	3	3	3	Y	YES
					PALPITATION				29/12/91	Detail	7	29/12/91	2	2	3	1	2	3	3	3	3		
										Detail	14	02/01/92	2	2	3	1	2	3	3	3	3		
										Summary	02/01/92	14	2	2	3	1	2	3	3	3	3	1	YES
					RASH ERYTHEMATOUS				01/02/92	Detail	42	01/02/92	3	2	3	1	2	3	3	3	3	Y	YES
										Summary	06/02/92(*)	42	3	2	3	1	2	3	3	3	3	Y	YES
					SIGHT INCREASED				24/12/91	Detail	0	24/12/91	2	1	6	1	2	3	3	3	1		NO
										Detail	21	16/01/92	2	1	6	1	2	3	3	3	3	1	
										Summary	16/01/92	21	2	1	6	1	2	3	3	3	3	1	
					IMPRIMANE				02/02/92	Detail	14	02/02/92	3	2	3	1	2	3	3	3	3		

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=fatal
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=kill present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (a) onset date missing; first report visit date used

1547

9550082

11

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PHARMACIA CNS RED
 REDOMETINE - PROTOCOL 20126/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End date	Last report visit	Sae	Hist ary	Rai ship	Stud drug	Sym treat	Dis app.	Re app.	Out app.	Skill some	
			Start date	End date															
2/1	51	Emipramine	02/02/92	15/03/92	10/02/92	Detail	21	23/02/92	21	3	2	3	1	YES	3	3	3	3	1
						Summary		23/02/92	Summary	21	3	2	3	1	YES	3	3	3	1
		DIARRHOEA			31/01/92	Detail	0	16/03/92(*)	0	2									NO
						Summary		16/03/92(*)	Summary	0	2								NO
		HYPOKALAEMIA			24/02/92	Detail	28	28/02/92	28	1	3	5	1		5	3	3	1	YES
						Summary		28/02/92	Summary	28	1	3	5	1	5	3	3	1	YES
		INSOMNIA			27/01/92(Q)	Detail	0	16/03/92(*)	0	3									NO
						Summary		16/03/92(*)	Summary	0	3								NO
		MOUTH DRY			11/02/92	Detail	14		14	1	2	3	1		3	3	3	3	YES
						Detail	21		21	1	2	3	1		3	3	3	3	YES
						Detail	28		28	1	2	3	1		2	3	3	3	YES
						Detail	35		35	1	2	3	1		2	3	3	3	YES
						Detail	42		42	1	2	3	1		2	3	3	3	YES
						Summary		16/03/92(*)	Summary	42	1	2	3	1	2	3	3	3	YES
		NAUSEA			09/02/92	Detail	14	13/02/92	14	2	2	3	1		3	3	3	1	YES
						Summary		13/02/92	Summary	14	2	2	3	1	3	3	3	1	YES
		RHAGADES			18/02/92	Detail	21	19/03/92	21	2	2	6	1	YES	2	3	3	1	YES
						Summary		19/03/92	Summary	21	2	2	6	1	YES	2	3	3	1
		VERTIGO			05/02/92	Detail	7	17/02/92	7	2	2	3	1		3	3	3	1	YES
						Summary		17/02/92	Summary	7	2	2	3	1	3	3	3	1	YES
2/2	45	Imipramine	18/04/91	16/05/91	20/04/91	Detail	7	20/04/91	7	2	1	3	1		2	3	3	1	YES
						Summary		20/04/91	Summary	7	2	1	3	1	2	3	3	1	YES
		HEADACHE			02/05/91	Detail	26	02/05/91	26	5	1	4		YES	2	3	3	1	YES

Sae: 1=0 unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening, 5= fatal
 Study drug: 1= no change, 2= dose reduced, 3= def. withdrawal, 4= temp. inter.
 Hospital: 1= requires, 2= not req., 3= not appl., 4= Outcome: 1= recovered, 2= rec. with seq., 3= still present, 4= death
 Disapp./Reapp.: 1= no, 2= yes, 3= not appl., 4= Relationship: 1= definite, 2= probable, 3= possible, 4= doubtful, 5= unknown, 6= none
 Symptomatic treatment: 0= no, 1= yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (Q) onset date missing: first report visit date used

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12

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PHARMACIA CMS RED
REDBETINE - PROTOCOL 20124/915
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit record	End No date	Last report visit	Save rcty	Hist ary	Rai ship	Stud drug	Symp tree	Dis Hosp	Ra app.	Out come	Skill Pres	Present (C)	
																						Summary
2/2	43	Imipramine	16/06/91	16/05/91	HEADACHE	02/05/91	Summary	02/05/91	28	3	1	4	YES	2	3	3	1	1	1	1	YES	
					HYPOTENSION POSTURAL	23/06/91	Detail	7 25/06/91	7	2	3	4		2	2	3	1	1	1	1	YES	
					INSOMNIA	18/06/91(C)	Detail	0 16/05/91(*)	0	2												NO
					MUSEA	25/06/91	Detail	7 25/06/91	7	2	1	3		2	3	3	1	1	1	1	1	YES
						02/05/91	Detail	28 02/05/91	28	3	1	3	1	YES	3	3	3	1	1	1	1	YES
						02/05/91	Summary	02/05/91	28	3	1	3	1	YES	3	3	3	1	1	1	1	YES
					RHINITIS	02/05/91	Detail	35 16/05/91(*)	35	2	1	3	1	2	3	3	3	1	1	1	1	YES
						19/01/91	Detail	0 29/08/91(*)	0	2												NO
					ANAEMLIA HYPOCHROMIC	26/08/91	Detail	42 29/08/91(*)	42	1	3	4	1	YES	2	3	3	3	3	3	3	YES
					CONSTIPATION	11/07/91(C)	Detail	0 29/08/91(*)	0	2												NO
					DYSPEPSIA	18/07/91	Detail	7 25/07/91	7	3	3	3	1	YES	2	3	3	1	1	1	1	NO
					FATIGUE	06/07/91	Detail	0 29/08/91(*)	0	2												NO
						02/05/91	Detail	35 16/05/91(*)	35	2	1	3	1	2	3	3	3	1	1	1	1	YES
						02/05/91	Summary	02/05/91	35	2	1	3	1	2	3	3	3	1	1	1	1	YES

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=indefinite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present; end date = visit date
(D) onset date missing; first report visit date used

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13

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PHARMACIA CMS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last report	Save visit	Hist ory	Re ship	Re Stud	Still Sympt	Dis app.	Re come	Still Present	
			Start date	End date														
2/2	44	Imipramine	19/07/91	29/08/91	04/07/91	Detail	0	29/08/91(*)	0	3								NO
						Summary												
					25/07/91	Detail	7			2	1	3	1		2	3	3	3
						Summary	14	28/07/91		2	1	3	1		2	3	3	1
						Summary			14	2	1	3	1		2	3	3	1
					19/05/91	Detail	8			2								
						Summary	21	04/08/91		2	1	3	1		2	3	3	1
						Summary			21	2	1	3	1		2	3	3	1
					22/07/91	Detail	7	25/07/91		3	2	3	1		2	3	3	1
						Summary	14	01/08/91		7	3	2	3	1	2	3	3	1
						Summary			14	2	2	3	1		2	3	3	1
					11/08/91	Detail	28	19/08/91		2	2	3	1		2	3	3	3
						Summary	35	19/08/91		35	2	2	3	1	2	3	3	1
						Summary			35	2	2	3	1		2	3	3	1
					22/07/91	Detail	7	26/07/91		1	1	4	1		2	3	3	1
						Summary	14	26/07/91		14	1	4	1		2	3	3	1
						Summary			14	1	1	4	1		2	3	3	1
					11/07/91(*)	Detail	0	29/08/91(*)		0	3							NO
						Summary												
					11/07/91(*)	Detail	0	29/08/91(*)		0	1							NO
						Summary												
45	Reboxetine	08/09/91	20/10/91	DYSPNOEA	01/10/91	Detail	26	05/10/91		1	2	4	1		2	3	3	1
						Summary	26	05/10/91		26	1	2	4	1	2	3	3	1

Serivity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(M) adverse event still present: end date = visit date
(*) onset date missing: first report visit date used

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PHARMACIA CNS RAD

REBOMETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Saw rcty	Hist ory	Re ship	Dis app.	Re app.	Out app.	Still present (C)			
																	08/09/91	20/10/91	05/10/91
2/2	45	Rebometine	08/09/91	20/10/91	GASTRITIS	05/10/91	Detail Summary	28	06/10/91	28	2	2	3	1	YES	2	3	1	YES
					HYPOTENSION POSTURAL	01/10/91	Detail Summary	28	08/10/91	35	3	2	3	1	2	3	3	3	3
					MOUTH DRY	13/09/91	Detail Summary	7	13/09/91	7	3	2	3	1	2	3	3	1	YES
					PHARYNGITIS		Detail Summary	0		1	1	1	3	1	3	3	3	3	3
					SINUSITIS	22/09/91	Detail Summary	21	29/09/91	21	2	1	6	1	2	3	3	1	YES
					INSOMNIA	17/09/91	Detail Summary	0	23/10/91	0	2								NO
					MOUTH DRY	30/09/91	Detail Summary	7	12/10/91	21	2	2	3	1	2	3	3	3	3
					NERVOUSNESS	07/10/91	Detail Summary	21	16/10/91	21	2	2	3	4	2	2	3	1	YES

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=critical
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=requires, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=yes, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (Q) onset date missing: first report visit date used

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REBOVETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit	End	Last report	Re	Dis	Re	Out	Still					
			Start date	End date															
2/2	47	Placebo	24/03/92	04/05/92	INSOMNIA	01/03/92	Detail	0	28/17/04/92	2	1	6	1	2	3	3	1	NO	
						Summary	17/04/92	20	2	1	6	1	2	3	3	1			
48	Rebovetine	17/04/92	19/05/92	CONSTITUTION	18/04/92	Detail	14	20/05/92(*)	14	2	2	2	1	2	3	3	3	Y	
					Summary	20/05/92(*)	14	2	2	2	1	2	3	3	3	Y			
2/3	36/A	Imipramine	07/03/91	17/04/91	INSOMNIA	03/04/92	Detail	0	28/25/04/92	3	1	6	1	2	3	3	1	NO	
						Summary	25/04/92	20	3	1	6	1	2	3	3	1			
2/3	36/A	Imipramine	07/03/91	17/04/91	INSOMNIA	11/04/92	Detail	7	35/09/05/92	2	2	2	1	2	3	3	3	YES	
						Summary	09/05/92	35	2	2	2	1	2	3	3	1			
2/3	36/A	Imipramine	07/03/91	17/04/91	INSOMNIA	06/04/91	Detail	35	17/04/91(*)	42	2	1	3	1	2	3	3	Y	
						Summary	17/04/91(*)	42	2	1	3	1	2	3	3	3	Y		
2/2	37	Rebovetine	27/03/91	07/05/91	INSOMNIA	22/03/91	Detail	21	17/04/91(*)	42	1	1	2	1	2	3	3	Y	
						Summary	17/04/91(*)	42	1	1	2	1	2	3	3	3	Y		
2/2	37	Rebovetine	27/03/91	07/05/91	INSOMNIA	20/03/91	Detail	0	07/05/91(*)	20	3	1	4	1	2	3	3	Y	
						Summary	07/05/91(*)	20	3	1	4	1	2	3	3	3	Y		
2/2	39	Imipramine	19/08/91	20/09/91	INSOMNIA	01/08/91	Detail	0	20/09/91	2								YES	
						Summary	20/09/91	2											YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=def. withdraw, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=free. with sup., 3=still present, 4=death
Disapp./reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present; end date = visit date
(D) onset date missing; first report visit date used

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PHARMACIA CNS RED

REBROXTINE - PROTOCOL 2026/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Center	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report		Disapp.	Recovery	Out	Still present	
										visit	date					
2/3	39	Imipramine	11/08/91	20/09/91	INSOMNIA	01/08/91	Detail	21	26/08/91	2	6	1	YES	2	3	1
							Summary		26/08/91	21	2	6	1	YES	2	3
40	Reboxetine	24/10/91	06/12/91	ANOREXIA	01/09/91	Detail	0	30/10/91	3	1	4	1	3	3	3	1
						Summary		30/10/91	7	3	1	4	1	3	3	1
		INSOMNIA			20/10/91	Detail	0	05/12/91(*)	2							NO
						Summary		05/12/91(*)	0	2						
		NAUSEA			29/10/91	Detail	7	30/10/91	2	1	4	1	YES	3	3	1
						Summary		30/10/91	7	2	1	4	1	YES	3	3
		VERTIGO			26/10/91	Detail	7	02/11/91	1	1	4	1	YES	2	3	5
						Summary		02/11/91	14	1	1	3	1	YES	2	3
		VOMITING			01/09/91	Detail	0	05/12/91(*)	2							NO
						Summary		05/12/91(*)	0	2						
41	Placebo		05/10/91	13/11/91	DIARRHOEA	06/10/91	Detail	7	09/10/91	2	1	4	1	2	3	1
							Summary		09/10/91	7	2	1	4	1	2	3
		FATIGUE			25/09/91(*)	Detail	0	16/11/91(*)	2							NO
						Summary		16/11/91(*)	0	2						
		HYPOTENSION			24/10/91	Detail	28	05/11/91	1	1	3	1	2	3	3	
						Summary		05/11/91	35	2	1	3	1	2	3	1
		LIBIDO DECREASED			25/09/91(*)	Detail	0	14/11/91(*)	3							NO
						Summary		14/11/91(*)	0	3						

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=none change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (*) adverse event used for statistical analysis
 (**) adverse event still present: end date = visit date
 (***) onset date missing: first report visit date used

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17

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PHARMACIA CMS RED

REDBOX - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Save	Hist	Rai	Stud	Sym	Dis	Re	Out	Skill	visit	rity	ary	ship	drug	tres	Hosp	app.	some	Present	(c)						
																															14	1	1	6	1	2
2/3	41	Placebo	03/10/91	13/11/91	PHARYNGITIS	18/10/91	Detail	14	17/10/91	14	1	1	6	1	2	3	3	1	YES																	
							Summary	17/10/91																												
42		Isipramine	19/05/92	30/06/92	HEADACHE	04/05/92	Detail	0																												
							Detail	7	26/05/92	2	2	1	6	1	2	3	3	1	NO																	
							Summary	26/05/92																												
							Detail	0																												
							Detail	35	22/06/92	2	2	1	6	1	3	3	3	1	NO																	
							Summary	22/06/92																												
							Detail	0																												
							Detail	35	30/06/92	3	3	1	5	1	2	3	3	3	Y																	
							Summary	30/06/92																												
							Detail	14																												
							Detail	21	08/06/92	2	2	1	4	1	2	3	3	1	YES																	
							Summary	08/06/92																												
							Detail	25																												
							Detail	42	26/06/92	2	2	1	5	1	2	3	3	1	YES																	
							Summary	26/06/92																												
							Detail	21	30/06/92	2	2	1	4	1	2	3	3	1	YES																	
							Summary	30/06/92																												
							Detail	0																												
							Detail	25	15/06/92	3	3	1	6	1	2	3	3	1	NO																	
							Summary	15/06/92																												
							Detail	21	30/06/92	2	2	1	3	1	2	3	3	1	YES																	
							Summary	30/06/92																												
							Detail	25																												
							Detail	42	26/06/92	2	2	1	4	1	2	3	3	1	YES																	
							Summary	26/06/92																												

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening, 5= fatal
 Study drug: 1= no change, 2= dose reduced, 3= def. withdrawn, 4= temp. inter.
 Hospital: 1= required, 2= not req., 3= not appl. -- Outcome: 1= recovered, 2= rec. with seq., 3= still present, 4= death
 Disapp./Reapp.: 1= no, 2= yes, 3= not appl. -- Relationship: 1= definite, 2= probable, 3= possible, 4= doubtful, 5= unknown, 6= none
 Symptomatic treatment: 0= no, 1= yes
 (C) adverse event used for statistical analysis
 (M) adverse event still present; end date = visit date
 (D) onset date missing; first report visit date used

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PHARMACIA DIS MSD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17-0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Saves rity	Mist ory	Rel ship	Stud drug	Sym tras	Dis app.	Re app.	Out come	Still present (c)			
																				Summary	Detail	Summary
2/3	42	Imipramine	19/05/92	30/06/92	VERTIGO	10/06/92	Summary	26/06/92	42	2	1	3	1	2	3	3	3	1	YES			
					VISION ABNORMAL	17/06/92	Detail	35	2	1	4	1	2	3	3	3	3	3				
						26/06/92	Detail	42	1	1	6	1	2	3	3	3	3	1				
						26/06/92	Summary	26/06/92	42	2	1	4	1	2	3	3	3	1		YES		
2/4	31	Placebo	26/03/91	05/05/91	INSOMNIA	17/03/91(D)	Detail	0	0	2										NO		
						17/03/91(D)	Summary	06/05/91(*)	0	2											NO	
32		Reboxetine	26/10/91	06/12/91	INSOMNIA	17/10/91(D)	Detail	0	0	2											NO	
						17/10/91(D)	Summary	06/12/91(*)	0	2												NO
33		Imipramine	23/05/91	10/07/91	GAHMA-6T INCREASED	21/05/91(D)	Detail	0	0	2											NO	
						21/05/91(D)	Summary	10/07/91(*)	0	2												NO
						INSOMNIA	21/05/91(D)	Detail	0	2												NO
						INSOMNIA	21/05/91(D)	Detail	42	2	1	6	1	YES	2	3	3	1				NO
						INSOMNIA	21/05/91(D)	Detail	42	2	1	6	1	YES	2	3	3	1				NO
						INSOMNIA	21/05/91(D)	Summary	10/07/91	42	2	1	6	1	YES	2	3	3	1			NO
35		Reboxetine	15/07/92	26/10/92	SECONDARY TONIC INFECTION	20/10/92(S)	Detail	42	1	1	6	1	2	3	3	3	3	3	3	3	YES	
						20/10/92(S)	Summary	27/10/92(*)	42	1	1	6	1	2	3	3	3	3	3	3	3	YES
36		Imipramine	12/02/92	26/03/92	INSOMNIA	12/01/92	Detail	0	0	0	1	6	1	2	3	3	3	3	3	1		NO
						12/01/92	Detail	35	17/03/92	0	1	6	1	2	3	3	3	3	3	1		NO
						17/03/92	Summary	17/03/92	35	0	1	6	1	2	3	3	3	3	3	1		NO
2/5	73	Placebo	07/02/92	21/03/92	INSOMNIA	15/01/92	Detail	0	0	2											Y	
						15/01/92	Summary	20/03/92(*)	0	2												Y
						MALADISE	25/02/92	Detail	21	25/02/92	2	1	5	1	3	3	3	3	3	1		YES
						MALADISE	25/02/92	Summary	25/02/92	21	2	1	5	1	3	3	3	3	3	1		YES

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=life threatening
 Study drug: 1=as change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcomes: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (D) onset date missing: first report visit date used
 (S) onset date missing: second report visit date used

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PHARMACIA CAS RED
REBOMETINE - PROTOCOL 20124-015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last report visit	Sae	Hist	Rel	Stud	Sympt	Dis app.	Re app.	Out app.	Still present (c)
			Start date	End date														
2/5	73	Placebo	07/02/92	20/05/92	12/02/92	Detail	7	16/02/92	7	2	2	5	1	3	3	3	1	YES
							Summary	16/02/92	7	2	2	5	1	3	3	3	1	
74	Reboactive	21/06/92	01/06/92	01/06/92	28/06/92	Detail	16	02/07/92	14	2	3	5	1	2	3	3	1	YES
							Summary	02/07/92	14	2	3	5	1	2	3	3	1	
75	Enipramine	11/09/92	11/09/92	22/10/92	21/06/92	Detail	7	10/07/92	21	2	2	3	1	2	3	3	1	YES
							Summary	10/07/92	21	2	2	3	1	2	3	3	1	
75	Enipramine	11/09/92	11/09/92	22/10/92	03/10/92	Detail	20	06/10/92	28	2	1	6	1	YES	3	3	1	YES
							Summary	06/10/92	28	2	1	6	1	YES	3	3	1	
76	Enipramine	15/09/92	15/09/92	26/10/92	26/09/92	Detail	16	28/09/92	14	2	1	4	1	YES	3	3	1	YES
							Summary	28/09/92	14	2	1	4	1	YES	3	3	1	
76	Enipramine	15/09/92	15/09/92	26/10/92	19/09/92	Detail	7	20/09/92	7	2	2	5	1	3	3	3	1	YES
							Summary	20/09/92	7	2	2	5	1	3	3	3	1	
76	Enipramine	15/09/92	15/09/92	26/10/92	28/10/92	Detail	99	26/11/92(*)	99	1	3	5	1	2	3	3	3	Y
							Summary	26/11/92(*)	99	1	3	5	1	2	3	3	3	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=none, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl.
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl.
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (c) onset date missing: first report visit date used

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20

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End No	date	Last report visit	Save any data	Hist any data	Rel. to drug	Stu. Sympt	Dis. app.	Re. app.	Out. app.	Still present (C)		
2/5	76	Imipramine	15/09/92	26/10/92		HYPOTENSION POSTURAL	09/10/92	Detail	28			3	3	2	1	YES	3	3	3	3	3	
								Detail	35	18/10/92		2	2	3	1		3	3	3	3	1	
								Summary		18/10/92	35	3	2	2	1	YES	3	3	3	3	1	YES
						TACHYCARDIA	19/09/92	Detail	7	20/09/92		1	2	3	1		3	3	3	3	1	YES
								Summary		20/09/92	7	1	2	3	1		3	3	3	3	1	YES
						TREMOR	06/10/92	Detail	28			2	2	3	1		3	3	3	3	3	
								Detail	35	18/10/92		2	2	3	1		3	3	3	3	1	YES
								Summary		18/10/92	35	2	2	3	1		3	3	3	3	1	YES
	78	Reboxetine	19/10/92	13/11/92		TREMOR	02/11/92	Detail	28			2	3	3	1		2	3	3	3	3	
								Detail	35	12/11/92		3	3	3	1		2	3	3	3	1	YES
								Summary		12/11/92	35	3	3	3	1		2	3	3	3	1	YES
2/6	55	Reboxetine	12/05/92	23/07/92		INSOMNIA	03/03/92	Detail	8			2	1	6	1	YES	5	3	3	3	3	
								Detail	7			2	1	6	1	YES	5	3	3	3	3	
								Detail	14	26/06/92		1	1	6	1	YES	3	3	3	3	1	NO
								Summary		26/06/92	14	2	1	6	1	YES	3	3	3	3	1	NO
	56	Reboxetine	12/06/92	23/07/92		INSOMNIA	01/03/92	Detail	8			2	1	6	1	YES	3	3	3	3	3	Y
								Detail	7			2	1	6	1	YES	3	3	3	3	3	Y
								Summary		26/07/92(4)	7	2	1	6	1	YES	3	3	3	3	3	Y
	57	Imipramine	05/05/92	15/06/92		CONSTIPATION	15/05/92	Detail	14			2	2	3	1		2	3	3	3	3	Y
								Summary		16/06/92(4)	14	2	2	3	1		2	3	3	3	3	Y
						DIZZINESS	10/06/92	Detail	42			2	2	3	1		3	3	3	3	3	Y
								Summary		16/06/92(4)	42	2	2	3	1		3	3	3	3	3	Y
						INSOMNIA	05/03/92	Detail	8			2										

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=free with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (2) onset date missing; first report visit date used

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21

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PHARMACIA CNS RED

REDBUETINE - PROTOCOL 20126/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Sae	Hist ary	Rai ship	Stud app.	Sym app.	Dis some	Re present	Out	Stcill						
																				15/05/92	16/05/92	17/05/92	18/05/92	19/05/92	20/05/92
2/6	57	Imipramine	05/05/92	15/06/92	INSOMNIA	05/05/92	Detail	7					2	1	6	1	YES	3	3	3					
							Detail	21	25/05/92																
							Summary	25/05/92																	
	58	Placebo	18/05/92	29/06/92	FATIGUE	05/06/92	Detail	21																	
							Detail	35	19/06/92																
							Summary	19/06/92																	
	59	Placebo	27/05/92	23/06/92	INSOMNIA	01/05/92	Detail	0																	
							Detail	7	16/05/92																
							Summary	16/05/92																	
	60	Imipramine	12/05/92	22/06/92	CONSTIPATION	22/05/92	Detail	14																	
							Detail	14	23/06/92																
							Summary	23/06/92																	
					DIIZZINESS	05/06/92	Detail	28																	
							Detail	28	23/06/92																
							Summary	23/06/92																	
					INSOMNIA	07/05/92	Detail	7																	
							Detail	7	23/06/92																
							Summary	23/06/92																	
					MOUTH DRY	22/05/92	Detail	14																	
							Detail	28																	
							Detail	35																	
							Detail	42																	

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (M) adverse event still present: end date = visit date
 (D) onset date missing: first report visit date used

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22

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last report visit	Saw rity	Hist ory	Rat	Rat	Stud	Somp	Dis app.	Re app.	Out app.	Still present (C)					
			Start date	End date																				
3/1	61	Imipramine	05/03/91	06/06/91	06/03/91	Detail	7			2	2	3	1	2	3	3	3	3	3					
						Detail	16			2	2	3	1	2	3	3	3	3	3					
						Detail	21				1	2	3	1	2	3	3	3	3	3				
						Detail	28				1	2	3	1	1	3	3	3	3	3				
						Detail	35	05/06/91			2	2	3	1	2	3	3	3	3	3	3			
			Summary		05/06/91			35	2	2	3	1	1	3	3	3	3	3	3	YES				
141	Pisicbe	SOMNOLENCE	06/03/91		06/03/91	Detail	7			2	2	3	1	2	3	3	3	3	3					
						Detail	35	05/06/91			1	2	3	1	2	3	3	3	3	3				
						Summary		05/06/91			35	2	2	3	1	2	3	3	3	3	3	YES		
			08/11/91	14/11/91	08/11/91	Detail	42	13/11/91			1	3	4	1	3	3	3	3	3	3	3	YES		
						Summary		13/11/91			42	1	3	4	1	3	3	3	3	3	3	3	YES	
143	Reboxetine	HERPES SIMPLEX	08/11/91		08/11/91	Detail	42	13/11/91			1	1	6	1	3	3	3	3	3	3	YES			
						Summary		13/11/91			42	1	1	6	1	3	3	3	3	3	3	YES		
			14/05/92	20/05/92	14/05/92	Detail	35	20/05/92(M)			2	2	3	1	3	3	3	3	3	3	3	YES		
						Summary		20/05/92(M)			35	2	2	3	1	3	3	3	3	3	3	3	YES	
			24/06/92		24/06/92	Detail	21				1	2	2	1	3	3	3	3	3	3	3	3		
			Detail	28					1	2	2	1	3	3	3	3	3	3	3	3				
			Detail	35	20/05/92(M)				35	1	2	2	1	3	3	3	3	3	3	3	YES			
			Summary		20/05/92(M)			35	1	2	2	1	3	3	3	3	3	3	3	3	YES			
144	Reboxetine	NERVOUSNESS	09/06/92	22/07/92	10/06/92	Detail	7			2	2	3	1	3	3	3	3	3	3	3				
						Detail	14				2	2	3	1	3	3	3	3	3	3	3			
						Detail	35				1	2	3	1	1	3	3	3	3	3	3	3	YES	
						Summary		22/07/92(M)			35	2	2	3	1	3	3	3	3	3	3	3	3	YES
			10/06/92		10/06/92	Detail	7				2	2	3	1	3	3	3	3	3	3	3	3	YES	
			Summary		22/07/92(M)			7	2	2	3	1	3	3	3	3	3	3	3	3	YES			

Severity: 0=unknown, 1=mlg, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (M) adverse event still present; end date = visit date
 (D) onset date missing; first report visit date used

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23

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PHARMACIA CNS RBD

REBOXTINE - PROTOCOL 2014/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

S/I	Centre	Patient	Drug	Treatment		Onset date	Type	Visit	End No date	Last report visit	Save Hist	Rel Stud	Sympt	DIG	Re	Out	Still	
				Start date	End date													
3/1	144	Reboxtine	09/06/92	22/07/92	VERTIGO	10/06/92	Detail	7		2	2	3	1	3	3	3	3	
						Detail	35		1	2	3	1	YES	3	3	3	3	
						Detail	42		1	2	3	1	YES	3	3	3	3	Y
						Summary	22/07/92(*)	42	2	2	3	1	YES	3	3	3	3	Y
451	Reboxtine	20/01/92	01/02/92	CONSTIPATION	22/01/92	Detail	7		2	1	1	3	YES	2	1	3	3	
					Detail	14		3	2	3	YES	2	1	3	3	Y		
					Summary	01/02/92(*)	14	3	1	1	3	YES	2	1	3	3	Y	
					Detail	14		2	1	4	3	YES	2	1	3	3	Y	
452	Placebo	22/01/92	04/03/92	VISION ABNORMAL	29/01/92	Detail	14		2	1	4	3	YES	2	1	3	3	
					Summary	04/03/92(*)	14	2	1	4	3	YES	2	1	3	3	Y	
					Detail	21		2	2	1	1	3	3	3	3	3		
					Detail	28		2	2	1	1	3	3	3	3	3		
453	Placebo	22/01/92	04/03/92	VISION ABNORMAL	31/01/92	Detail	21		2	2	1	1	3	3	3	3	3	
					Detail	35		1	2	1	1	3	3	3	3	3		
					Detail	42		1	2	1	1	3	3	3	3	Y		
					Summary	04/03/92(*)	42	2	2	1	1	3	3	3	3	Y		
455	Imipramine	29/01/92	10/03/92	CONSTIPATION	31/01/92	Detail	7		2	1	2	1	2	3	3	3	3	
					Detail	14		2	1	2	1	YES	2	3	3	3		
					Detail	21		1	1	2	1	YES	3	3	3	3		
					Detail	28		1	1	2	1	YES	3	3	3	3		
454	Reboxtine	17/02/92	01/06/92	URINARY RETENTION	06/02/92	Detail	14		1	3	2	1	3	3	3	3	3	
					Detail	21		1	3	2	1	3	3	3	3	3		
					Detail	28		1	3	2	1	3	3	3	3	3		
					Summary	11/02/92(*)	42	1	3	2	1	3	3	3	3	Y		

Severities: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(*) onset date missing: first report visit date used

9550082

24

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report			Dis Hosp	Re app.	Out app.	Still present (c)				
										visit	date	type								
3/1	454	Reboxetine	17/02/92	01/06/92	URINARY RETENTION	20/02/92	Detail	28			1	2	1	1	3	3	1			
							Detail	35												
							Summary	42	27/03/92	42	1	2	1	1	3	3	3	1	YES	
							Summary	27/03/92												
3/1	454	Isipramine	25/03/92	03/06/92	CHEST PAIN PRECORDIAL	03/06/92	Detail	14	03/06/92	14	3	2	3	3	3	3	1	YES		
							Summary	03/06/92												
							Detail	7			2	1	2	1	YES	3	3	3	Y	
							Summary	03/06/92(*)			7	2	1	2	1	YES	3	3	3	Y
3/2	55/A	Reboxetine	29/01/91	11/05/91	SWEATING INCREASED	27/05/92	Detail	7			1	2	2	1	3	3	3	Y		
							Summary	03/06/92(*)			7	1	2	2	1	3	3	3	Y	
							Detail	7			1	2	2	1	3	3	3	3	Y	
							Summary	03/06/92(*)			7	1	2	2	1	3	3	3	Y	
3/2	55/A	Reboxetine	29/01/91	11/05/91	SWEATING INCREASED	03/06/92	Detail	14	03/06/92	14	3	2	3	1	2	3	3	1	YES	
							Summary	03/06/92			14	3	2	3	1	2	3	3	1	YES
							Detail	14	03/06/92	14	3	2	2	3	2	2	2	3	1	YES
							Summary	03/06/92			14	3	2	2	3	2	2	3	1	YES
3/2	55/A	Reboxetine	29/01/91	11/05/91	SWEATING INCREASED	31/01/91	Detail	7			1	2	4	1	5	3	3	3		
							Summary	03/06/92(*)			7	1	2	4	1	5	3	3	3	
							Detail	14			1	2	4	1	5	3	3	1	YES	
							Summary	15/02/91			21	1	2	4	1	5	3	1	YES	
3/3	57	Placebo	16/07/91	26/09/91	INSOMNIA	31/01/91	Detail	7	03/02/91	7	1	1	3	1	5	3	1	YES		
							Summary	03/02/91			7	1	1	3	1	5	3	1	YES	
							Detail	0												
							Summary	03/02/91			7	1	1	3	1	5	3	1	YES	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=fatal
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (d) onset date missing; first report visit date used

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25

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PHARMACIA CHS RD

REBOVETINE - PROTOCOL 29124/915
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Save rity	Hist ary	Rep. app.	Stud. app.	Sympt. app.	Dis. app.	Re. app.	Out. app.	Still present (c)	
																					15/07/91 (2)
3/3	67	Placebo	15/07/91	25/05/91	INSOMNIA	15/07/91 (2)	01/08/91	Detail	20	24/02/91	7	2	1	6	1	YES	3	3	3	1	NO
								Detail	35			3	1	5	1	YES	3	3	3	3	
								Detail	42			3	1	5	1	YES	3	3	3	3	Y
								Summary		20/05/91 (1*)	42	3	1	5	1	YES	3	3	3	3	Y
								Detail	28			2	2	3	1		3	3	3	3	
								Detail	35	20/05/91	35	2	2	3	1		3	3	3	1	YES
								Summary			35	2	2	3	1		3	3	3	1	
59	Rebovetine		21/01/92	02/05/92	HOT FLASHES	05/02/92		Detail	21			2	2	2	1		2	3	3	3	
								Detail	28			2	2	2	1		2	3	3	3	
								Detail	35			1	2	2	1		2	3	3	3	
								Detail	42			1	2	2	1		2	3	3	3	Y
								Summary		02/03/92 (1*)	42	2	2	2	1		2	3	3	3	Y
								Detail	7	24/01/92	7	2	2	3	1		3	3	3	1	YES
								Summary		24/01/92	7	2	2	3	1		3	3	3	1	
								Detail	7	24/01/92	7	2	2	3	1		3	3	3	1	YES
								Summary		24/01/92	7	2	2	3	1		3	3	3	1	
59	Placebo		04/02/92	16/05/92	AGITATION	29/02/92		Detail	20	01/03/92	20	3	2	5	1	YES	3	3	3	1	YES
								Summary		01/03/92	20	3	2	5	1	YES	3	3	3	1	
								Detail	0		0	0									NO
								Summary		16/05/92 (1*)	0	0									
								Detail	7	14/12/92	7	3	1	4	1		3	3	3	3	
								Detail	14	12/02/92	14	3	1	4	1		3	3	3	1	YES
								Summary		12/02/92	14	3	1	4	1		3	3	3	1	
								Detail	0		0	0									NO
								Summary		16/05/92 (1*)	0	0									
								Detail	0		0	0									NO
								Summary		16/05/92 (1*)	0	0									

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=cure, with sak., 3=still present, 4=death
Disapp./reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(c) adverse event used for statistical analysis
(*) adverse event still present; end date = visit date
(2) onset date missing; first report visit date used

1562

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24

PHARMACIA CNS RED
 REMOETINE - PROTDICOL 20124/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centra Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Save file	Hist ary	Rel ship	Stud drug	Sympt treat	Hosp app.	Dis app.	Re app.	Out come	Still present (C)		
																			7	8
3/5 69	Placebo	06/02/92	16/05/92	HEADACHE	05/02/92	Detail	7	05/02/92		2	1	4	1	3	3	3	1	YES		
						Summary	Summary	05/02/92		7	2	1	4	1	3	3	1	YES		
				INSOMNIA	29/01/92	Detail	0			3										
						Detail	7			3	1	5	1	YES	3	3	3			
						Detail	14			2	1	5	1	YES	3	3	3			
						Detail	21			2	1	5	1	YES	3	3	3			
						Detail	28			3	1	5	1	YES	3	3	3			
						Detail	35			2	1	5	1	YES	3	3	3			
						Detail	42			1	1	5	1	YES	3	3	3	Y		
						Summary	Summary	16/05/92(1*)		42	3	1	5	1	YES	3	3	3	Y	
						Summary	Summary			42	3	1	5	1	YES	3	3	3	Y	
						Detail	7	09/02/92		2	2	3	1	3	3	3	1	YES		
				PARAESTHESIA	05/02/92	Detail	7	09/02/92		2	2	3	1	3	3	3	1	YES		
						Summary	Summary	09/02/92		7	2	2	3	1	3	3	3	1	YES	
				SUICIDE ATTEMPT	30/01/92(3)	Detail	0			3										
						Summary	Summary	16/05/92(1*)		0	3	1	5	1	YES	3	3	3	NO	
						Detail	28			3	1	5	1	YES	3	3	3	1	NO	
						Detail	35			3	1	5	1	YES	3	3	3	1	YES	
						Summary	Summary	05/05/92		35	3	1	5	1	YES	3	3	3	1	YES
						Detail	0			3										
						Detail	7			3	1	6	1	YES	3	3	3	3		
						Detail	14			3	1	6	1	YES	3	3	3	3		
						Detail	21			3	1	6	1	YES	2	3	3	3		
						Detail	28			3	1	6	1	YES	2	3	3	3		
						Detail	35			3	1	6	1	YES	2	3	3	3		
						Detail	42			3	1	6	1	YES	2	3	3	3	Y	
						Summary	Summary	26/05/92(1*)		42	3	1	6	1	YES	2	3	3	Y	
						Summary	Summary	26/05/92(1*)		42	3	1	6	1	YES	2	3	3	Y	
						Detail	21	25/06/92		2	2	2	1	3	3	3	1	YES		
						Summary	Summary	25/06/92		21	2	2	2	1	3	3	3	1	YES	
						Detail	0			3										
				INSOMNIA	01/02/92	Detail	0			3										

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=indefinite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present: and date = visit date
 (3) onset date missing: first report visit date used

1563

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27

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PHARMACIA CNS RBD

REBOMETINE - PROTOCOL 2024/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Type record	Visit No	End date	Last report visit	Sev	Hist	Rel	Stud	Symp	Dis app.	Re Hosp	Out app.	Still								
			Start date	End date																							
3/3	70	Isipramine	15/04/92	26/05/92	01/02/92	INSOMNIA	Detail	7		3	1	6	1	YES	3	3	3	3	3	3							
							Detail	14		3	1	6	1	YES	3	3	3	3	3	3	3	3	3	3			
							Detail	21		2	1	6	1	YES	2	3	3	3	3	3	3	3	3	3	3		
							Detail	28		2	1	6	1	YES	2	3	3	3	3	3	3	3	3	3	3		
							Detail	35		2	1	6	1	YES	2	3	3	3	3	3	3	3	3	3	3	3	
							Detail	42		2	1	6	1	YES	2	3	3	3	3	3	3	3	3	3	3	3	
							Summary			26/05/92(*)	42	3	1	6	1	YES	2	3	3	3	3	3	3	3	3	3	3
							Detail	7		1	2	2	1	3	3	3	3	3	3	3	3	3	3	3	3	3	
							Detail	14		1	2	2	1	3	3	3	3	3	3	3	3	3	3	3	3	3	
							Detail	21		1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	
							Detail	28		1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	
							Detail	35		1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	
							Detail	42		1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	
							Summary			26/05/92(*)	42	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3
71	Isipramine	16/04/92	27/05/92	18/04/92	SWEATING INCREASED	Detail	7		2	2	2	1	3	3	3	3	3	3	3	3							
						Detail	14		2	2	2	1	3	3	3	3	3	3	3	3	3	3					
						Detail	21		1	4	2	2	1	3	3	3	3	3	3	3	3	3	3				
						Detail	28		1	4	2	2	1	3	3	3	3	3	3	3	3	3	3				
						Detail	35		1	4	2	2	1	3	3	3	3	3	3	3	3	3	3	3			
						Detail	42		1	4	2	2	1	3	3	3	3	3	3	3	3	3	3	3			
						Summary			26/05/92(*)	42	1	4	2	2	1	3	3	3	3	3	3	3	3	3	3		
						Detail	7		2	2	2	1	3	3	3	3	3	3	3	3	3	3	3	3			
						Detail	14		2	2	2	1	3	3	3	3	3	3	3	3	3	3	3	3			
						Detail	21		1	4	2	2	1	3	3	3	3	3	3	3	3	3	3	3			
						Detail	28		1	4	2	2	1	3	3	3	3	3	3	3	3	3	3	3			
						Detail	35		1	4	2	2	1	3	3	3	3	3	3	3	3	3	3	3			
						Detail	42		1	4	2	2	1	3	3	3	3	3	3	3	3	3	3	3			
						Summary			25/04/92	42	1	4	2	2	1	3	3	3	3	3	3	3	3	3	3		
71	Isipramine	16/04/92	27/05/92	24/04/92	DIZZINESS	Detail	7		2	2	3	1	3	3	3	3	3	3	3	3							
						Detail	14		1	2	3	1	2	3	3	3	3	3	3	3	3	3					
						Detail	21		1	2	3	1	2	3	3	3	3	3	3	3	3	3					
						Detail	28		1	2	3	1	2	3	3	3	3	3	3	3	3	3					
						Detail	35		1	2	3	1	2	3	3	3	3	3	3	3	3	3					
						Detail	42		1	2	3	1	2	3	3	3	3	3	3	3	3	3					
						Summary			18/05/92	28	2	2	3	1	2	3	3	3	3	3	3	3	3				
						Detail	7		1	1	6	1	YES	2	3	3	3	3	3	3	3	3					
						Detail	14		2	1	6	1	YES	3	3	3	3	3	3	3	3	3					
						Detail	21		1	1	6	1	YES	3	3	3	3	3	3	3	3	3					
						Detail	28		1	1	6	1	YES	2	3	3	3	3	3	3	3	3					
						Detail	35		1	1	6	1	YES	2	3	3	3	3	3	3	3	3					
						Detail	42		1	1	6	1	YES	2	3	3	3	3	3	3	3	3					
						Summary			27/05/92(*)	42	3	1	6	1	YES	2	3	3	3	3	3	3	3				

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
 Study drug: 1=no change, 2=data reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (*) adverse event used for statistical analysis
 (†) adverse event still present; end date = visit date
 (‡) onset date missing; first report visit date used
 (§) onset date unknown; report treatment date by patient visit

1564

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28

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PHARMACIA CNS RED
 REBOMETINE - PROTOCOL 20124/015
 Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

S/N	Patient ID	Drug	Treatment Start date	End date	Adverse event	Onset date	Type		Last report visit	Hist. visit	Rel. to drug	Study drug	Dis. app.	Re. app.	Out. app.	Still present (C)				
							record	No date												
3/3	71	Imipramine	14/06/92	27/06/92	HEADACHE	07/05/92(8)	Summary	13/05/92(1*)	28	1	1	6	1	YES	2	3	3	3	YES	
					MOUTH DRY	19/06/92	Detail	7	1	2	3	1	3	3	3	3	3	3	3	3
							Detail	14	1	2	3	1	3	3	3	3	3	3	3	3
							Detail	21	1	2	3	1	2	3	3	3	3	3	3	3
							Detail	28	1	2	3	1	2	3	3	3	3	3	3	3
							Detail	35	1	2	3	1	2	3	3	3	3	3	3	3
							Detail	42	1	2	3	1	2	3	3	3	3	3	3	3
							Summary	27/05/92(1*)	42	1	2	3	1	2	3	3	3	3	3	3
							Detail	0	2	1	6	1	YES	3	3	3	3	3	3	3
							Detail	7	2	1	6	1	YES	3	3	3	3	3	3	3
							Detail	14/01/00/92	2	1	6	1	YES	3	3	3	3	3	3	3
							Summary	01/06/92	14	2	1	6	1	YES	3	3	3	3	3	3
							Detail	42	2	2	3	1	2	3	3	3	3	3	3	3
							Summary	17/06/91(1*)	42	2	2	3	1	2	3	3	3	3	3	3
							Detail	0	2	1	3	1	3	3	3	3	3	3	3	3
							Summary	17/06/91(1*)	0	2	1	3	1	3	3	3	3	3	3	3
							Detail	7	1	1	3	1	3	3	3	3	3	3	3	3
							Summary	17/06/91(1*)	7	1	1	3	1	3	3	3	3	3	3	3
							Detail	21	2	2	3	1	2	3	3	3	3	3	3	3
							Detail	28	2	2	3	1	2	3	3	3	3	3	3	3
							Detail	35	2	2	3	1	2	3	3	3	3	3	3	3
							Detail	42	1	2	3	1	2	3	3	3	3	3	3	3
							Summary	17/06/91(1*)	42	2	2	3	1	2	3	3	3	3	3	3
							Detail	14/05/91	14	2	2	3	1	3	3	3	3	3	3	3
							Summary	17/05/91	14	2	2	3	1	3	3	3	3	3	3	3
							Detail	21	2	2	3	1	2	3	3	3	3	3	3	3
							Detail	28	2	2	3	1	2	3	3	3	3	3	3	3

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. --- Outcome: 1=recovered, 2=free, with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. --- Relationship: 1=indefinite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (1) adverse event still present: end date = visit date
 (2) onset date missing: first report visit date used

1565

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29

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PHARMACIA CMS RED

REBOMETINE - PROTOCOL 2024/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End date	Last report visit	Sae	Hist	Rai	Stud	Symp	Dis	Re	Out	Skill	
			Start date	End date															
3/4	79	Imipramine	06/05/91	15/06/91	15/06/91	VISION ABNORMAL	35	06/06/91	06/06/91	85	2	2	3	1	3	3	3	1	YES
80		Imipramine	01/09/91	26/09/91	16/09/91	DIZZINESS	21	25/09/91(*)		21	2	2	3	3	3	3	3	3	Y
						VISION ABNORMAL													
82		Placebo	17/06/91	28/07/91	07/06/91	INSOMNIA	21	01/07/91		21	2	1	4	1	3	3	3	1	NO
85		Placebo	17/06/91	26/06/91	19/06/91	AGITATION	7	24/06/91(*)		7	3	2	3	1	2	3	3	3	Y
						DIARRHOEA													
						INSOMNIA													
						TREMOR													
85		Imipramine	29/10/91	08/12/91	26/10/91(*)	INSOMNIA	9	09/12/91(*)		9	2								NO
						MOUTH DRY													

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=steep. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with see., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (*) adverse event used for statistical analysis
 (c) adverse event still present; end date = visit date
 (d) onset date missing; first report visit date used

1566

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30

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PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20154/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit record	End No date	Last report visit	Sev	Hist ary	Rel ship	Rea	Stud	Symp	Dis app.	Re code	Out come	Still Present (C)								
3/4	85	Isipramine	08/12/91 MOUTH DRY	29/10/91	08/12/91	MOUTH DRY	01/11/91	Detail	14	84/11/91	14	1	2	3	1	3	3	3	3	3	3	1	YES						
								Summary																					
								Detail	14/11/91	Detail	21	20/11/91	20	1	2	3	1	2	3	3	3	3	3	3	1	YES			
								Summary																					
								Detail	16/11/91	Detail	21	09/12/91(*)	42	1	2	3	1	1	3	3	3	3	3	3	3	1	YES		
								Summary																					
								Detail	16/11/91	Detail	21				1	2	3	1	1	3	3	3	3	3	3	3	1	YES	
								Summary																					
								Detail	16/11/91	Detail	28				1	2	3	1	2	3	3	3	3	3	3	3	1	YES	
								Summary																					
								Detail	16/11/91	Detail	42				1	2	3	1	1	3	3	3	3	3	3	3	1	YES	
								Summary																					
87	Placebo	19/01/92 HYPERTONIA	50/10/91	02/11/91	VERTIGO	50/10/91	Detail	7	02/11/91	7	1	2	3	1	3	3	3	3	3	3	3	1	YES						
							Summary																						
							Detail	01/01/92	Detail	28			2	2	5	1	2	3	3	3	3	3	3	3	1	YES			
							Summary																						
							Detail	18/01/92	Detail	42			2	2	5	1	2	3	3	3	3	3	3	3	1	YES			
							Summary																						
88	Placebo	06/05/92 AGITATION	29/05/92	06/05/92	AGITATION	29/05/92	Detail	7	31/05/92	14	1	2	3	1	2	3	3	3	3	3	3	1	YES						
							Summary																						
							Detail	10/06/92	Detail	21			3	1	3	1	2	3	3	3	3	3	3	3	1	YES			
							Summary																						
							Detail	26/05/92	Detail	28			3	1	3	1	2	3	3	3	3	3	3	3	3	1	YES		
							Summary																						
89	Rebasetina	06/05/92 INSOMNIA	26/05/92	06/05/92	INSOMNIA	26/05/92	Detail	42	01/05/92	42	3	1	3	1	2	3	3	3	3	3	3	3	1	YES					
							Summary																						

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=fatal
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (**) onset date missing: first report visit date used

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31

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOMETINE - PROCTOOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Save rity	Hist ory	Re ship	Rai app.	Stud tras	Sym app.	Dis Hosp	Re come	Out app.	Skill present	C	
																					21
3/4 89	Rebometine	26/03/92	06/05/92	TACHYCARDIA	18/04/92	Detail	21														
						Summary		17/06/92	28	2	2	3	1	2	3	3	3	3	3	3	3
90	Rebometine	26/04/92	06/06/92	NICTURITION DISORDER	01/05/92	Detail	7														
						Detail	42	03/06/92		1	2	3	1	2	3	3	3	3	3	3	3
						Summary		03/06/92	42	1	2	3	1	2	3	3	3	3	3	3	3
458	Rebometine	26/05/92	09/08/92	HEADACHE	06/06/92	Detail	14														
						Summary		06/06/92	14	2	1	4	1	1	1	1	1	1	1	1	1
						Detail	7														
						Summary		09/06/92(*)	7	2	2	3	1	1	1	1	1	1	1	1	1
459	Plicoba	02/06/92	13/07/92	BACK PAIN	28/05/92	Detail	7														
						Summary		09/06/92(*)	7	2	2	3	1	1	1	1	1	1	1	1	1
						Detail	21	22/06/92		2	1	8	1	1	1	1	1	1	1	1	1
						Summary		22/06/92	21	2	1	8	1	1	1	1	1	1	1	1	1
						Detail	21	13/07/92(*)		2	1	3	1	1	1	1	1	1	1	1	1
						Summary		13/07/92(*)	21	2	1	3	1	1	1	1	1	1	1	1	1
						Detail	7														
						Summary		13/07/92(*)	7	2	2	3	1	1	1	1	1	1	1	1	1
						Detail	21	22/06/92		1	1	6	1	1	1	1	1	1	1	1	1
						Summary		22/06/92	21	1	1	6	1	1	1	1	1	1	1	1	1

Serious: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=life threatening
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(D) onset date missing: first report visit date used

1568

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32

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOMETINE - PROTOCOL 2016/0115
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End No date	Last report visit	Solve rity	Hist ory	Re ship	Re drug	Dis app.	Re come	Skill Present (c)		
			Start date	End date														
3/4	460	Rebometine	19/08/92	20/08/92	19/08/92	CONFUSION	Detail	7 22/08/92	7	3	2	2	3	2	2	3	1	
			Summary	22/08/92	7	3	2	2	3	2	2	3	1	YES				
			19/08/92		19/08/92	DRY	Detail	7 22/08/92	7	2	2	2	3	2	2	3	1	YES
			Summary	22/08/92	7	2	2	3	2	2	3	1	YES					
			18/09/92		18/09/92	DIZZINESS	Detail	7 24/09/92(*)	7	3	2	3	1	2	3	3	3	Y
			Summary	24/09/92(*)	7	3	2	3	1	2	3	3	Y					
	461	Imipramine	18/09/92		18/09/92	DRY	Detail	7 24/09/92(*)	7	3	2	3	1	2	3	3	Y	
			Summary	24/09/92(*)	7	3	2	3	1	2	3	3	Y					
			18/09/92		18/09/92	NAUSEA	Detail	7 24/09/92(*)	7	2	2	3	1	2	3	3	3	Y
			Summary	24/09/92(*)	7	2	2	3	1	2	3	3	Y					
			15/09/92		15/09/92	INCREASED SWEATING	Detail	7 24/09/92(*)	7	3	2	3	1	2	3	3	3	Y
			Summary	24/09/92(*)	7	3	2	3	1	2	3	3	Y					
	462	Imipramine	01/10/92	06/10/92	01/10/92	DEPERSONALIZATION	Detail	7 06/10/92(*)	7	3	2	3	1	2	3	3	Y	
			Summary	06/10/92(*)	7	3	2	3	1	2	3	3	Y					
			05/10/92		05/10/92	DYSPNOEA	Detail	7 06/10/92	7	2	2	3	1	2	3	3	1	YES
			Summary	06/10/92	7	2	2	3	1	2	3	3	1	YES				
			02/10/92		02/10/92	HYPERTENSIA	Detail	7 06/10/92(*)	7	2	2	3	1	2	3	3	3	Y
			Summary	06/10/92(*)	7	2	2	3	1	2	3	3	Y					
			02/10/92		02/10/92	INSOMNIA	Detail	7 06/10/92(*)	7	3	2	3	1	2	3	3	Y	
			Summary	06/10/92(*)	7	3	2	3	1	2	3	3	Y					

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl.
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl.
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (S) onset date missing; first report visit date used

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33

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PHARMACIA CNS RED

RESONETINE - PROTOCOL 20124/915
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Onset date	Type	Visit record	End No date	Last report visit	Save	Hist	Rel	Stu	Symp	Dis	Re	Out	Still			
			date	date	date				visit	date	ry	ship	drug	tra	Hosp	app.	app.	some	present	(C)	
4/1	91	Imipramine	12/10/91	22/11/91	10/11/91	FATIGUE	35 42 Summary	23/11/91(*)	42	2	2	3	1	2	3	3	3	3	3	3	Y
					20/10/91	HOT FLUSHES	14 21 Summary	30/10/91	21	2	2	3	1	2	3	3	3	3	3	3	Y
					04/10/91(2)	INSOMNIA	9 7 Summary	23/11/91(*)	0	3	2	1	3	1	2	3	3	3	3	3	NO
					15/10/91		14 21 28 35 42 Summary														
					26/10/91	MOUTH DRY	21 28 35 42 Summary	23/11/91(*)	42	3	2	3	1	2	3	3	3	3	3	3	Y
					30/10/91	Nausea	21 28 Summary	05/11/91	28	2	3	3	1	2	3	3	3	3	3	3	Y
					09/11/91	PARAESTHESIA	29 35 Summary	15/11/91	55	2	3	3	1	2	3	3	3	3	3	3	Y
					19/10/91	SOMNOLENCE	7 Summary	16/10/91		2	2	3	1	2	3	3	3	3	3	3	Y

Seravity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=def. withdraw, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcom: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(2) onset date missing: first report visit date used

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34

PHARMACIA CNS R&D
REBOZATINE - PROTOCOL 20124/915
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Adverse event	Last report visit	Save any drug	Hist drug	Rel. area	Stu drug	Symp	Dis app.	Re app.	Out	Still present (C)		
			Start date	End date																	
6/1	91	Imipramine	12/19/91	22/11/91	SOMNOLENCE	Summary	16/10/91		7	2	2	3	1	2	3	3	1	3	1	YES	
			16/10/91		SWEATING INCREASED	Detail 7			7	2	3	1		2	3	3		3		3	
						Detail 14			14	2	3	1		2	3	3		3		3	
						Summary	23/11/91(*)		14	2	2	5	1		2	3	3		3		Y
						Detail 7			7	2	2	3	1		2	3	3		3		3
						Detail 14			14	2	2	3	1		2	3	3		3		3
						Detail 21			21	2	2	3	1		2	3	3		3		3
						Detail 28	25/07/91		28	2	2	3	1		2	3	3		3		3
						Summary	25/07/91		28	2	2	3	1		2	3	3		3		3
						Detail 0			0	1											NO
						Summary	16/10/91(*)		0	1											NO
						Detail 7			7	2	1	6	1		2	3	3		3		3
						Detail 14			14	2	1	6	1	YES	2	3	3		3		3
						Detail 21	25/09/91		21	2	1	6	1		3	3	3		3		3
						Detail 25	09/91		25	2	1	6	1	YES	2	3	3		3		3
						Summary	25/09/91		21	2	1	6	1	YES	2	3	3		3		3
						Detail 7			7	2	1	6	1		2	3	3		3		3
						Detail 21	25/09/91		21	2	1	6	1		3	3	3		3		3
						Summary	25/09/91		21	2	1	6	1		2	3	3		3		3
						Detail 42			42	2	2	3	1		2	3	3		3		3
						Summary	16/10/91(*)		42	2	2	3	1		2	3	3		3		3
						Detail 7			7	3	2	3	3		2	1	3		3		3
						Detail 21	25/09/91		21	2	1	6	1		3	3	3		3		3
						Summary	25/09/91		21	2	1	6	1		2	3	3		3		3
						Detail 42			42	2	2	3	1		2	3	3		3		3
						Summary	16/10/91(*)		42	2	2	3	1		2	3	3		3		3
						Detail 7			7	3	2	3	3		2	1	3		3		3
						Summary	23/05/92(*)		7	3	2	3	3		2	1	3		3		3
						Detail 7			7	3	3	3	5		2	1	3		3		3
						Summary	23/05/92(*)		7	3	2	3	5		2	1	3		3		3
						Detail 7			7	3	3	3	5		2	1	3		3		3
						Summary	23/05/92(*)		7	3	3	3	5		2	1	3		3		3
						Detail 7			7	3	2	3	3		2	1	3		3		3
						Summary	19/05/92		7	3	2	3	3		2	1	3		3		3
						Detail 7			7	3	3	3	5		2	1	3		3		3
						Summary	19/05/92		7	3	3	3	5		2	1	3		3		3
						Detail 7			7	3	3	3	5		2	1	3		3		3
						Summary	19/05/92		7	3	3	3	5		2	1	3		3		3
						Detail 7			7	3	2	3	3		2	1	3		3		3
						Summary	19/05/92		7	3	2	3	3		2	1	3		3		3

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening, 5= fatal
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (W) adverse event still present; end date = visit date
 (D) onset date missing; first report visit date used
 (R) onset date missing; first report visit date used

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35

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PHARMACIA, CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Save rfcy	Hist ory	Rel ship	Stud Sym	Dis app.	Re app.	Out app.	Skill																																
																		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
4/1	116	Imipramine	16/05/92	22/05/92	VERTIGO	19/05/92	Summary		23/05/92(*)	7	3	2	3	3	2	1	3	3	Y																														
117		Imipramine	05/09/91	16/10/91	APPETITE INCREASED	06/09/91	Detail	7		1	2	3	1	2	3	3	3	3	Y																														
							Detail	14		1	2	3	1	2	3	3	3	3	Y																														
							Detail	21		2	3	1	2	3	3	3	3	3	Y																														
							Detail	28		2	3	1	2	3	3	3	3	3	Y																														
							Detail	35		2	3	1	2	3	3	3	3	3	Y																														
							Detail	42		2	3	1	2	3	3	3	3	3	Y																														
							Summary	15/10/91(*)	42	2	2	3	1	2	3	3	3	3	Y																														
							Detail	7		2	2	3	1	2	3	3	3	3	Y																														
							Detail	14	10/09/91	2	2	3	1	2	3	3	3	3	Y																														
							Summary	10/09/91	14	2	2	3	1	2	3	3	3	3	Y																														
							Detail	7		1	2	3	1	2	3	3	3	3	Y																														
							Detail	14	12/09/91	1	2	3	1	2	3	3	3	3	Y																														
							Summary	12/09/91	14	1	2	3	1	2	3	3	3	3	Y																														
							Detail	42		2	2	3	1	2	3	3	3	3	Y																														
							Summary	15/10/91(*)	42	2	2	3	1	2	3	3	3	3	Y																														
149		Reboxetine	30/09/92	10/11/92	NAUSEA	30/09/92	Detail	7		3	2	3	1	2	3	3	3	3	Y																														
							Detail	21	19/10/92	2	2	3	1	2	3	3	3	3	Y																														
							Summary	19/10/92	21	3	2	3	1	2	3	3	3	3	Y																														
4/3	99	Placebo	06/08/91	15/08/91	DIARRHOEA	19/08/91	Detail	7		2	2	3	1	2	3	3	3	3	Y																														
							Detail	14	21/08/91	2	2	3	1	2	3	3	3	3	Y																														
							Summary	21/08/91	14	2	2	3	1	2	3	3	3	3	Y																														
							Detail	7		2	2	3	1	2	3	3	3	3	Y																														
							Detail	14	21/08/91	2	2	3	1	2	3	3	3	3	Y																														
							Summary	21/08/91	14	2	2	3	1	2	3	3	3	3	Y																														

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=critical
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with set., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=None
 Symptomatic Treatment: 0=No, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; and date = visit date
 (Q) onset date missing; first report visit date used

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PARACETA CNS RED
REDOXTINE - PROTOCOL 2016/9115
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Onset date	Type	Visit record	End No date	Last			Dis app.	Re app.	Out app.	Still presant (C)			
									report visit	His	Sym							
									visit	fty	ory	Hosp app.	app.	com	Presant (C)			
4/3	100	Imipramine	27/11/91	17/12/91	NAUSEA		7		2	2	3	1	2	3	3			
							14		2	2	3	1	3	3	3			
							Summary	21	2	2	3	3	2	2	3	1	YES	
									21	2	2	3	3	2	2	3	1	YES
			06/12/91		SWEATING INCREASED		14		2	2	3	1	2	3	3			
							21		2	2	3	3	2	2	3	1		
							Summary	21	2	2	3	3	2	2	3	1	YES	
			06/12/91		TREMOR		14		2	2	3	1	2	3	3			
							21		2	2	3	3	2	2	3	1		
							Summary	21	2	2	3	3	2	2	3	1	YES	
			30/11/91		VERTIGO		7		2	2	3	1	2	3	3			
							14		2	2	3	1	2	3	3			
							Summary	21	2	2	3	3	2	2	3	1	YES	
			10/06/91		NAUSEA		7		2	2	3	1	2	3	3			
							28		2	2	3	1	2	3	3	1		
							Summary	28	2	2	3	3	2	2	3	1	YES	
110	Imipramine	15/06/91	26/07/91		HEADACHE		8		2									
							14		1	1	6	1	3	3	3			
							Summary	21	2	1	6	1	3	3	3	1	NO	
			07/07/91		MOUTH DRY		28		1	2	3	1	3	3	3			
							35		1	2	3	1	3	3	3			
							Summary	42	1	2	3	1	3	3	3	3	Y	
			08/07/91		SWEATING INCREASED		26		1	2	2	1	3	3	3			
							35		1	2	3	1	3	3	3			
							Summary	42	1	2	3	1	3	3	3	3	Y	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=skill present, 4=death
 Disapp./Resp.: 1=yes, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (S) onset date missing: first report visit date used

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37

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PHARMACIA CMS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End date	Last report visit	Saw rity	Hist cry	Rat ship	Rai drug	Stud treat	Symp app.	Dis app.	Re app.	Dut app.	Still app.			
			Start date	End date																		
6/4	110	Imipramine	15/06/91	26/07/91	06/07/91	DETAIL	42	26/07/91(*)	42	1	2	3	1	3	3	3	3	3	3	Y		
						SUMMARY															YES	
	111	Imipramine	04/07/91	14/08/91	20/06/91	DETAIL	0	14/08/91(*)	0	2											NO	
						SUMMARY																NO
	112	Placebo	10/07/91	20/08/91	01/06/91	DETAIL	0	20/08/91(*)	0	2											NO	
						SUMMARY																NO
	113	Reboxetine	31/08/91	11/10/91	30/09/91	DETAIL	35	05/10/91	35	1	2	5	1	YES	3	3	3	3	3	3	1	YES
						SUMMARY																YES
	114	Placebo	26/11/91	31/12/91	29/12/91	DETAIL	42	29/12/91	42	1	2	3	1	3	3	3	3	3	3	3	1	YES
						SUMMARY																YES
	175	Imipramine	13/02/92	25/03/92	14/02/92	DETAIL	7		7	2	2	3	1	YES	3	3	3	3	3	3	3	3
						SUMMARY																YES

1374

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
Study drug: 1=as change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=skill present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(D) onset date missing: first report visit date used

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

36

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PHARMACIA OAS R&D
REBOMETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End No date	Last report visit	Save rity	Hist any	Rel ship	Stud drug	Symp treat	Dis app.	Re app.	Out come	Still present (C)	
			Start date	End date															
4/4	175	Imipramine	15/02/92	25/02/92	15/02/92	Detail	21	05/05/92	21	2	2	3	1	3	3	3	1	YES	
						Summary													
						Summary													
	176	Placebo	08/04/92	08/04/92	08/04/92	Detail	26	10/06/92(18)	26	3	1	6	3	1	1	3	3	Y	
						Summary													
						Summary													
	177	Imipramine	08/04/92	11/05/92	08/04/92	Detail	26	08/04/92	26	3	2	6	3	1	2	3	2	YES	
						Summary													
						Summary													
	178	Reboxetine	08/06/92	08/06/92	08/06/92	Detail	21	18/05/92	21	2	2	3	3	3	2	3	1	YES	
						Summary													
						Summary													
	179	Placebo	11/09/92	29/09/92	07/09/92	Detail	0		5									Y	
						Detail	7												
						Summary													

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=none, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (2) onset date missing: first report visit date used

1575

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39

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PHARMACIA CNS RED
REBOCETINE - PROTOCOL 20124/015
Listing No.: 17.3

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Save any drug	Hist	Rel	Dis app.	Re app.	Out	Still	Sympt	Dose present (C)															
																				report	visit	any	drug	treat	app.	app.	dose	present	(C)					
4/4	179	Placebo		11/09/92	29/09/92	SUICIDE ATTEMPT	29/09/92	Detail	21	29/09/92	21	1	1	5	3	YES	1	2	3	1	YES													
																						Summary	29/09/92	21	1	1	5	3	YES	1	2	3	1	YES
180	Rebocetine			07/10/92	17/11/92	HYPOTENSION	03/11/92	Detail	20	18/11/92	2	1	3	1	YES	3	3	3	3	1	YES													
																						Detail	35	18/11/92	2	2	3	1	YES	3	3	3	1	YES
																						Summary	19/11/92	35	2	1	3	1	YES	3	3	3	1	YES
5/1	127	Rebocetine		06/06/91	17/07/91	HYPERURICAEMIA	31/09/92	Detail	0	03/11/92	2	2	4	1	YES	3	3	3	3	1	NO													
																						Detail	7	03/11/92	2	2	4	1	YES	3	3	3	1	NO
																						Summary	03/11/92	28	2	2	4	1	YES	3	3	3	1	NO
128	Rebocetine			14/06/91	25/07/91	HYPOTENSION POSTURAL	27/06/91	Detail	21	18/07/91	5	2	3	1	3	3	3	3	3	1	YES													
																						Detail	42	18/07/91	5	2	3	1	3	3	3	1	YES	
																						Summary	18/07/91	42	5	2	3	1	3	3	3	1	YES	
128	Rebocetine			14/06/91	25/07/91	HYPOTENSION POSTURAL	02/06/91(a)	Detail	0	27/06/91(a)	2	1	5	1	3	3	3	3	3	1	NO													
																						Detail	21	27/06/91(a)	2	1	5	1	3	3	3	1	NO	
																						Summary	27/06/91(a)	21	2	1	5	1	3	3	3	1	NO	
128	Rebocetine			14/06/91	25/07/91	HYPOTENSION POSTURAL	15/06/91	Detail	7	06/07/91	2	2	3	1	3	3	3	3	3	1	YES													
																						Detail	14	06/07/91	2	2	3	1	3	3	3	1	YES	
																						Summary	06/07/91	28	2	2	3	1	2	3	3	1	YES	
128	Rebocetine			01/05/91	15/06/91	INSOMNIA	01/05/91	Detail	0	17/06/91	2	2	1	5	1	3	3	3	1	NO														
																					Detail	7	17/06/91	2	1	5	1	3	3	1	NO			
																					Summary	17/06/91	7	2	1	5	1	3	3	1	NO			
128	Rebocetine			15/06/91	15/06/91	TACHYCARDIA	15/06/91	Detail	7	15/06/91	2	2	3	1	3	3	3	3	3	1	NO													
																						Detail	14	15/06/91	2	2	3	1	3	3	3	1	NO	
																						Summary	15/06/91	14	2	2	3	1	3	3	3	1	NO	

Severities: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=na change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=free, with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=suspect, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(a) onset date missing: first report visit date used

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40

9550082

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 2016/915
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End No date	Last report visit	Save rity	Hist ory	Rel. app. app.	Stu. app. app.	Sym. app. app.	Dis. app. app.	Re. app. app.	Out. app. app.	Still present (c)			
			Start date	End date																	
5/1	126	Reboxetine	14/06/91	25/07/91	15/06/91	TACHYCARDIA	21	30/06/91	21	2	2	3	1	3	3	3	3	1	YES		
							Summary														
130	Placebo	Placebo	05/05/92	15/06/92	12/05/92	SINUSITIS	14	07/06/92	35	3	2	5	1	YES	3	3	3	1	YES		
							Summary														
132	Imipramine	Imipramine	25/06/92	01/08/92	19/07/92	MUSCLE CONTRACTIONS INVOL.	28	10/08/92(*)	42	2	2	4	1	2	3	3	3	3	YES		
							Summary														
5/2	125	Reboxetine	28/01/91	18/03/91	16/02/91	INSOMNIA	21		2	2	3	1	2	3	3	3	3	3			
							Detail														
							Summary														
5/3	184	Reboxetine	04/12/91	16/01/92	14/12/91	SWEATING INCREASED	14		2	2	2	1	3	3	3	3	3	3			
							Detail														
							Summary														
135	Imipramine	Imipramine	10/01/92	20/02/92	07/02/92	ACCOMMODATION ABNORMAL	45	20/02/92	42	2	2	2	1	2	3	3	3	1	YES		
							Detail														
							Summary														
5/3	184	Reboxetine	04/12/91	16/01/92	14/12/91	SWEATING INCREASED	14		2	2	2	1	3	3	3	3	3	3			
							Detail														
							Summary														
135	Imipramine	Imipramine	10/01/92	20/02/92	07/02/92	ACCOMMODATION ABNORMAL	45	20/02/92	42	2	2	2	1	2	3	3	3	1	YES		
							Detail														
							Summary														
5/3	184	Reboxetine	04/12/91	16/01/92	14/12/91	SWEATING INCREASED	14		2	2	2	1	3	3	3	3	3	3			
							Detail														
							Summary														
135	Imipramine	Imipramine	10/01/92	20/02/92	07/02/92	ACCOMMODATION ABNORMAL	45	20/02/92	42	2	2	2	1	2	3	3	3	1	YES		
							Detail														
							Summary														
5/3	184	Reboxetine	04/12/91	16/01/92	14/12/91	SWEATING INCREASED	14		2	2	2	1	3	3	3	3	3	3			
							Detail														
							Summary														
135	Imipramine	Imipramine	10/01/92	20/02/92	07/02/92	ACCOMMODATION ABNORMAL	45	20/02/92	42	2	2	2	1	2	3	3	3	1	YES		
							Detail														
							Summary														
5/3	184	Reboxetine	04/12/91	16/01/92	14/12/91	SWEATING INCREASED	14		2	2	2	1	3	3	3	3	3	3			
							Detail														
							Summary														
135	Imipramine	Imipramine	10/01/92	20/02/92	07/02/92	ACCOMMODATION ABNORMAL	45	20/02/92	42	2	2	2	1	2	3	3	3	1	YES		
							Detail														
							Summary														
5/3	184	Reboxetine	04/12/91	16/01/92	14/12/91	SWEATING INCREASED	14		2	2	2	1	3	3	3	3	3	3			
							Detail														
							Summary														
135	Imipramine	Imipramine	10/01/92	20/02/92	07/02/92	ACCOMMODATION ABNORMAL	45	20/02/92	42	2	2	2	1	2	3	3	3	1	YES		
							Detail														
							Summary														

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=fatal
 Study drug: 1=one change, 2=once reduced, 3=def. withdrawal, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 1=no, 2=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (G) onset date missing: first report visit date used

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PHARMACIA OMS RED

REBOMETINE - PROTOCOL 2012/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End No data	Last report visit rity	Hist any slisp	Rel drug app.	Stu tree	Somp Hosp	Dis app.	Re come	Out app.	Skill Present
			Start date	End date													
5/3	135	Imipramine	10/01/92	20/02/92	MOUTH DRY	Detail	21	20/02/92(*)	21	2	2	1	3	3	3	3	Y
					SWEATING INCREASED	Summary	35		42	2	2	1	2	3	3	3	Y
					TREMOR	Detail	21	13/02/92	55	2	2	1	3	3	3	3	Y
					WEIGHT INCREASE	Summary	42		42	2	2	1	2	3	3	3	Y
136	Imipramine	02/03/92	12/04/92	CONSTIPATION	Detail	7	13/04/92(*)	7	2	1	3	1	3	3	3	3	Y
					SWEATING INCREASED	Summary	7		7	2	1	3	1	3	3	3	Y
137	Reboxetine	15/05/92	25/06/92	CONSTIPATION	Detail	14	25/06/92(*)	14	2	2	3	1	2	3	3	3	Y
					MOUTH DRY	Summary	14		14	2	1	3	1	2	3	3	Y
					SWEATING INCREASED	Detail	0		14	2	1	3	1	2	3	3	Y
						Summary	14		14	2	1	3	1	2	3	3	Y

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=na change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(D) onset date missing: first report visit date used

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42

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/915
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit record	End No date	Last report visit	Save rty	Hist ary	Rel ship	Stud drug	Symp area	Dis app.	Re app.	Out come	Still present (c)									
6/1	151	Isipramine	21/01/92	29/01/92	ASTHENIA	26/01/92	Detail	7	26/01/92(*)	7	3	2	3	1	2	3	3	3	3	3	Y								
							Summary																			Y			
							Detail	7	26/01/92(*)	7	3	2	3	1	2	3	3	3	Y										
							Summary																					Y	
							Detail	7	26/01/92(*)	7	3	2	3	1	2	3	3	3	Y										
							Summary																					Y	
							Detail	0		0	3																	NO	
							Summary																						
							Detail	7	26/01/92(*)	7	3	2	3	1	2	3	3	3	Y										
							Summary																						Y
152	Reboxetine	24/02/92	07/06/92	CONSTIPATION	25/02/92	Detail	7																						
						Summary																							
						Detail	14	08/03/92	14	2	2	4	1	2	3	3	1	YES											
						Summary																							
						Detail	14	08/03/92	14	2	2	4	1	2	3	3	1	YES											
						Summary																							
						Detail	55	03/04/92	55	2	3	6	1	YES	2	3	3	1	YES										
						Summary																							
						Detail	0		0	3																		NO	
						Summary																							
152	Reboxetine	24/02/92	07/06/92	CONSTIPATION	25/02/92	Detail	7																						
						Summary																							
						Detail	14	08/03/92	14	2	2	4	1	2	3	3	1	YES											
						Summary																							
						Detail	14	08/03/92	14	2	2	4	1	2	3	3	1	YES											
						Summary																							
						Detail	55	03/04/92	55	2	3	6	1	YES	2	3	3	1	YES										
						Summary																							
						Detail	0		0	3																		NO	
						Summary																							
152	Reboxetine	24/02/92	07/06/92	CONSTIPATION	25/02/92	Detail	7																						
						Summary																							
						Detail	14	08/03/92	14	2	2	4	1	2	3	3	1	YES											
						Summary																							
						Detail	14	08/03/92	14	2	2	4	1	2	3	3	1	YES											
						Summary																							
						Detail	55	03/04/92	55	2	3	6	1	YES	2	3	3	1	YES										
						Summary																							
						Detail	0		0	3																		NO	
						Summary																							
152	Reboxetine	24/02/92	07/06/92	CONSTIPATION	25/02/92	Detail	7																						
						Summary																							
						Detail	14	08/03/92	14	2	2	4	1	2	3	3	1	YES											
						Summary																							
						Detail	14	08/03/92	14	2	2	4	1	2	3	3	1	YES											
						Summary																							
						Detail	55	03/04/92	55	2	3	6	1	YES	2	3	3	1	YES										
						Summary																							
						Detail	0		0	3																		NO	
						Summary																							

Specify: 0=unknown, 1=mild, 2=moderate, 3=severe, -- History: 1=present before, 2=not observe bef., 5=unknown
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not app. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(c) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(9) onset date missing: first report visit date used

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43

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PHARMACIA CMS RED

REBOXETINE - PROTOCOL 2014/015
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Type record	Visit No	End date	Last report visit	Sae	Hist	Rai	Stud	Symp	Dis	Re	Dut	Still					
			Start date	End date																				
9/1	152	Reboxetine	26/02/92	07/06/92	04/05/92	SINUSITIS	Detail	14	88/03/92	14	2	3	6	1	YES	2	3	3	1	YES				
							Summary		88/03/92		14	2	3	6	1	YES	2	3	3	1	YES			
							Detail	TREMOR		7														
							Detail		14	89/03/92		1	2	4	1	2	3	3	3	3	3			
							Summary			89/03/92		14	1	2	4	1	2	3	3	3	1	YES		
							Detail		0															
							Detail		21															
							Detail		28															
							Detail		35															
							Summary		42		29/06/91(*)		42	2	1	4	1	5	3	3	3	Y		
153	Reboxetine	18/03/91	27/06/91	CONSTIPATION	HEADACHE	Detail	0																	
						Detail	7																	
						Detail	14																	
						Detail	21																	
						Detail	28																	
						Detail	35																	
						Detail	42																	
						Summary																		
						Detail	0																	
						Summary																		
154	Imipramine	30/05/92	06/06/92	INSOMNIA	INSOMNIA	Detail	0																	
						Summary																		
						Detail	0																	
						Detail	7																	
						Summary																		
						Detail	0																	
						Detail	7																	
						Summary																		
						Detail	0																	
						Summary																		

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. With set., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (*) adverse event used for statistical analysis
 (**) adverse event still present: end date = visit date
 (***) onset date missing: first report visit date used

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44

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PHARMACIA CMS RED
REBOXTINE - PROCTOOL 2014/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit End No date	Last report visit	Sev	Hist ary	Rai ship	Stud drug	Symp tres	Dis app.	Re come	Out app.	Still Pres	Skill Pres	
																					Summary
6/1	155	Placebo	05/07/92	04/05/92	HYPERKINESIA	17/07/92	Detail	14	04/05/92(*)	14	2	2	3	1	2	3	3	3	3	Y	YES
					INSOMNIA	01/06/92	Detail	0	04/05/92(*)	0	3										NO
	156	Placebo	05/09/92	19/10/92	NAUSEA	10/09/92	Detail	7		1	2	3	1	2	3	3	3	3	3		YES
						14/09/92	Detail	14		1	2	3	1	2	3	3	3	3	3		
						18/09/92	Summary	14		1	2	3	1	2	3	3	3	3	3		
6/2	157	Reboxetine	30/04/91	10/06/91	CONSTIPATION	05/05/91	Detail	14		2	2	3	1	2	3	3	3	3	3		YES
						21/04/91	Detail	21	14/05/91	2	2	3	1	2	3	3	3	3	3		
						14/05/91	Summary	14		2	2	3	1	2	3	3	3	3	3		
						DYSURIA	01/05/91	Detail	7		2	2	3	1	2	3	3	3	3		YES
						08/05/91	Detail	14	08/05/91	14	2	2	3	1	2	3	3	3	3		
						08/05/91	Summary	14		2	2	3	1	2	3	3	3	3	3		
						INSOMNIA	21/04/91(2)	Detail	0	10/06/91(*)	2										NO
						01/05/91	Detail	7	01/05/91	3	1	3	1	2	3	3	3	3	3		
						01/05/91	Summary	7	01/05/91	7	3	1	3	1	2	3	3	3	3		
						TREMOR	21/04/91(2)	Detail	0	05/05/91	1										YES
						05/05/91	Detail	7	05/05/91	7	2	1	3	1	2	3	3	3	3		
						05/05/91	Summary	7		2	1	3	1	2	3	3	3	3	3		
158		Imipramine	24/11/91	05/01/92	MOUTH DRY	10/12/91	Detail	21	18/12/91	2	1	3	1	2	3	3	3	3	3		YES
						18/12/91	Detail	28	18/12/91	2	1	3	1	2	3	3	3	3	3		
						18/12/91	Summary	28		2	1	3	1	2	3	3	3	3	3		
159		Imipramine	14/07/91	24/06/91	HYPERTENSION		Detail	0		2											Y
							Detail	7													

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with ack., 3=still present, 4=death
Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 1=no, 1=yes
(c) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(2) onset date missing: first report visit date used

1581

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45

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

6/2	159	Imipramine	14/07/91	24/08/91	HYPERTENSION	Onset date	Type record	Visit No	End date	Last report visit	Sv	Hst	Rel	Stud	Sympt	Dis app.	Re app.	Out app.	Skill	Y	NO	
																						Start date
						07/07/91(2)	Summary	7	24/08/91(*)	7	2											
			12/07/91		INSOMNIA		Detail	0														
							Detail	7														
							Summary	7	24/08/91(*)	7	1											
	160	Placebo	24/11/91	04/01/92	INSOMNIA	23/11/91	Detail	7														
							Detail	21														
							Detail	28														
							Detail	35														
							Detail	42														
							Summary	04/01/92(*)	42	2	1	3	1	YES	2	3	3	3	3	3	Y	NO
	161	Reboxetine	26/02/92	18/03/92	HEADACHE	21/02/92	Detail	7														
							Detail	14														
							Detail	21	10/03/92	1	2	3	1	1	5	3	3	3	3	3		
							Detail	21	10/03/92	1	2	3	1	2	3	3	1	1	3	3		
							Summary	10/03/92	21	2	2	5	1	1	3	3	1	1	3	3	1	YES
							Detail	7														
							Detail	21	19/03/92(*)	2	2	3	1	2	3	3	3	3	3	3	Y	YES
							Summary	19/03/92(*)	21	2	2	3	1	2	3	3	3	3	3	3	Y	YES
							Detail	21														
							Detail	28														
							Summary	19/03/92(*)	28	2	1	6	3	YES	2	1	3	3	3	3	Y	YES
	169	Imipramine	26/12/91	15/01/92	DYSPEA	01/12/91	Detail	7	02/01/92	1	2	3	1	2	3	3	3	3	3	1		YES
							Summary	02/01/92	7	1	2	3	1	2	3	3	3	3	3	3	1	YES
							Detail	7	31/12/91	1	2	3	1	2	3	3	3	3	3	3	1	YES
							Summary	31/12/91	7	1	2	3	1	2	3	3	3	3	3	3	1	YES
							Detail	14														
							Summary	01/08/92	14	2	2	5	1	YES	3	3	3	3	3	3	3	3

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=free, with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (w) adverse event still present; end date = visit date
 (2) onset date missing; first report visit date used

1582

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46

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PHARMACIA DNS RED

REBOXetine - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End No date	Last report visit	Save Hist	Rat	Stud Samp	Dis Hosp	Re app.	Out app.	Still present (C)						
			Start date	End date																		
6/2	171	Imipramine	22/07/92	01/09/92	01/08/92	ABDOMINAL PAIN	21	11/08/92	21	2	2	3	1	3	3	3	1					
			Summary				11/08/92	21	2	2	3	1	YES	3	3	3	1	YES				
			Detail				21	11/08/92	21	2	2	3	1	3	3	3	1	YES				
			Summary				11/08/92	21	2	2	3	1	YES	3	3	3	1	YES				
			Detail				35	20/08/92	20/08/92	MOUTH DRY	35	20/08/92	35	2	2	3	1	2	3	3	3	
			Summary				20/08/92	35	20/08/92	MOUTH DRY	35	20/08/92	35	2	2	3	1	2	3	3	3	
			Detail				42	01/09/92(*)	01/09/92(*)	SPEECH DISORDER	42	01/09/92(*)	42	2	2	3	1	2	3	3	3	
			Summary				01/09/92(*)	42	01/09/92(*)	SPEECH DISORDER	42	01/09/92(*)	42	2	2	3	1	2	3	3	3	
			Detail				28	15/08/92	15/08/92	SPEECH DISORDER	28	15/08/92	28	1	2	3	1	3	3	3	3	
			Summary				15/08/92	28	15/08/92	SPEECH DISORDER	28	15/08/92	28	1	2	3	1	3	3	3	3	
172	Reboxetine	07/07/92	17/08/92	17/08/92	CONSTIPATION	14	18/08/92(*)	14	2	2	3	1	3	3	3	3	3					
						Summary		18/08/92(*)	14	2	2	3	1	3	3	3	3	3	3			
						Detail		21	05/08/92	05/08/92	TREMOR	21	05/08/92	21	2	2	3	1	3	3	3	
						Summary		05/08/92	21	05/08/92	TREMOR	21	05/08/92	21	2	2	3	1	3	3	3	
						Detail		28	25/08/92	25/08/92	TREMOR	28	25/08/92	28	1	2	3	1	3	3	3	
						Summary		25/08/92	28	25/08/92	TREMOR	28	25/08/92	28	1	2	3	1	3	3	3	
						Detail		35	25/08/92	25/08/92	TREMOR	35	25/08/92	35	2	2	3	1	3	3	3	
						Summary		25/08/92	35	25/08/92	TREMOR	35	25/08/92	35	2	2	3	1	3	3	3	
						Detail		14	15/07/92	15/07/92	FATIGUE	14	15/07/92	14	2	2	3	1	3	3	3	
						Summary		15/07/92	14	15/07/92	FATIGUE	14	15/07/92	14	2	2	3	1	3	3	3	
6/3	163	Reboxetine	08/08/91	08/08/91	ANXIETY	7	08/08/91	7	5	2	3	3	2	2	2	3	1					
						Summary		08/08/91	7	5	2	3	3	2	2	3	1	YES				
						Detail		0	01/06/91	01/06/91	TACHYCARDIA	0	01/06/91	0	2	2	3	1	3	3		
						Summary		01/06/91	0	01/06/91	TACHYCARDIA	0	01/06/91	0	2	2	3	1	3	3		
						Detail		16	13/07/92	13/07/92	MOUTH DRY	16	13/07/92	16	2	2	3	1	3	3	3	
						Summary		13/07/92	16	13/07/92	MOUTH DRY	16	13/07/92	16	2	2	3	1	3	3	3	
						Detail		35	18/08/92(*)	18/08/92(*)	MOUTH DRY	35	18/08/92(*)	35	3	3	3	1	3	3	3	
						Summary		18/08/92(*)	35	18/08/92(*)	MOUTH DRY	35	18/08/92(*)	35	3	3	3	1	3	3	3	
						Detail		7	08/08/91	08/08/91	ANXIETY	7	08/08/91	7	5	2	3	3	2	2	3	1
						Summary		08/08/91	7	08/08/91	ANXIETY	7	08/08/91	7	5	2	3	3	2	2	3	1

Sever: 0=1 unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (e) onset date missing; first report visit date used

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

47

9550082

PHARMACIA CNS RED		REBOXETINE - PROTOCOL 2012/015		Listing No.: 17.0		ADVERSE EVENTS: DETAIL AND SUMMARY															
Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report	Sve	Hist rity	Rel ship	Stud app.	Svyp tres	Dis Hosp	Re app.	Out come	Skill present	(c)
8/3	163	Reboxetine	06/06/91	08/06/91	TACHYCARDIA	01/04/91	Summary	88/06/91	7	3	1	3	3	2	2	3	1	YES			
					VERTIGO	06/06/91	Detail	88/06/91	7	3	2	3	3	2	2	3	1	YES			
							Summary	88/06/91	7	3	2	3	3	2	2	3	1	YES			
164	Empiramine	11/10/91	21/11/91	HEADACHE	14/10/91	Detail	7	2	2	4	1	2	3	3	3	3					
						Detail	14	2	2	4	1	2	3	3	3	3	1	YES			
						Summary	22/10/91	14	2	2	4	1	2	3	3	3	1	YES			
					MOUTH DRY	09/11/91	Detail	35	2	2	2	1	3	3	3	3	3				
						Detail	42	2	2	2	1	3	3	3	3	3	3	Y			
						Summary	22/11/91(*)	42	2	2	2	1	3	3	3	3	3	Y			
					MYALGIA	14/10/91	Detail	7	2	2	4	1	2	3	3	3	3				
						Detail	14	2	2	4	1	2	3	3	3	3	1	YES			
						Summary	22/10/91	14	2	2	4	1	2	3	3	3	1	YES			
					TREMOR	09/11/91	Detail	85	2	2	2	1	3	3	3	3	3				
						Detail	42	2	2	2	1	3	3	3	3	3	3	Y			
						Summary	22/11/91(*)	42	2	2	2	1	3	3	3	3	3	Y			
165	Empiramine	18/10/91	26/11/91	ECOSINOPHILIA	26/11/91	Detail	42	2	2	3	1	2	3	3	3	3	3	Y			
						Summary	26/11/91(*)	42	2	2	3	1	2	3	3	3	3	Y			
					ONAMA-GT INCREASED	26/11/91	Detail	42	2	2	3	1	2	3	3	3	3	Y			
						Summary	26/11/91(*)	42	2	2	3	1	2	3	3	3	3	Y			
					MOUTH DRY	07/10/91(*)	Detail	9	1	1	1	1	1	1	1	1	1	NO			
						Summary	28/11/91(*)	9	1	1	1	1	1	1	1	1	1	NO			
						Detail	14	2	1	3	1	3	3	3	3	3	3				
						Detail	21	1	1	3	1	3	3	3	3	3	3				
						Detail	28	18/11/91	1	1	3	1	3	3	3	3	3	1			

Seracity: Sunknown, 1= mild, 2= moderate, 3= severe, 4= very severe, 5= fatal
 Study drug: 1= no change, 2= dose reduced, 3= def. withdrawn, 4= temp. inter.
 Hospital: 1= required, 2= not req., 3= not appl. -- Outcome: 1= recovered, 2= free, with seq., 3= still present, 4= death
 Disapp./Reapp.: 1= no, 2= yes, 3= not appl. -- Relationship: 1= definite, 2= probable, 3= possible, 4= doubtful, 5= unknown, 6= none
 Symptomatic treatment: 0= no, 1= yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (O) onset date missing; first report visit date used

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

46

9550082

PHARMACIA DAS RED
REBOXTIME - PROTOCOL 20124/015
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Saw any	Hist. rty	Rel. drug	Stud. trm	Symp. app.	Dis. app.	Re. app.	Du. app.	Still present (C)													
																				Summary	Detail	Summary	Detail	Summary	Detail	Summary	Detail	Summary	Detail			
6/3	165	Imipramine	16/10/91	26/11/91	MOUTH DRY	16/10/91	Summary	10/11/91	28	2	1	3	1	3	3	3	3	1	YES													
																				PHOSPHATASE ALKALINE INCR	26/11/91	42	2	2	3	1	2	3	3	3	3	Y
6/3	166	Reboxetine	25/10/91	29/11/91	HYPOTENSION	01/06/91	Detail	9	30/10/91(*)	0	1								NO													
																				INSOMNIA	29/10/91	7	2	2	5	3	3	1	3	3	Y	
																																Summary
6/3	167	Placebo	16/11/91	27/12/91	SOMNOLENCE	19/11/91	Detail	7	14	27/11/91	2	2	3	1	3	3	3	1	YES													
																				SUICIDE ATTEMPT	29/10/91	7	3	2	5	3	3	1	3	3	Y	
																																Summary
6/3	168	Placebo	03/12/91	06/01/92	CONSTIPATION	24/11/91(*)	Detail	9	66/01/92(*)	0	2								NO													
																				MOUTH DRY	24/12/91	26	2	2	3	1	3	3	3	3	Y	
																																Summary

Seriousness: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening, 5= fatal
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=free, with ser., 3=still present, 4=each
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present: and date = visit date
 (**) onset date missing: first report visit date used

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

49

9550082

PHARMACIA CNS RED
REDBETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last report visit	See any ship	Hist drug	Rel. app.	Stud. app.	Symp. app.	Disapp.	Re-appe.	Out. app.	Skill. app.			
			Start date	End date																	
6/3	168	Placebo	05/12/91	06/01/92	26/12/91	Detail	35	06/01/92(1)	35	2	2	3	1	3	3	3	3	3	Y		
			Summary																		
			26/12/91	Detail	28	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
			26/12/91	Detail	35	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
			Summary																		
			SOMNOLENCE																		
	505	Empiramine	05/12/91	17/12/91	31/12/91	Detail	35	06/01/92(1)	35	2	2	5	1	3	3	3	3	3	3	Y	
			Summary																		
			SUICIDE ATTEMPT																		
			TREMOR																		
			MOUTH DRY																		
			INSOMNIA																		
506	Placebo	06/01/92	19/02/92	06/12/91	Detail	14	17/12/91(1)	14	3	2	3	1	3	3	3	3	3	3	Y		
		Summary																			
		06/12/91	Detail	7	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y	
		06/12/91	Detail	14	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y	
		Summary																			
		MOUTH DRY																			
	507	Empiramine	06/01/92	24/02/92	27/01/92	Detail	21	08/02/92	35	3	2	3	1	3	3	3	3	3	3	Y	
			Summary																		
			SOMNOLENCE																		
			CONSTIPATION																		
			MOUTH DRY																		
			INSOMNIA																		

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=free, with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (D) adverse event still present; end date = visit date
 (E) onset date missing; first report visit date used

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

50

9550082

PHARMACIA CNS RD
REBORETINE - PROTDOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Type record	Visit End No date	Last report visit	Hist rel ship	Symp app.	Dis app.	Re come	Out presat	Still (c)					
			Start date	End date																
6/3	507	Isipramine	14/01/92	24/02/92	11/02/92	CONSTIPATION	Detail	42	24/02/92	42	1	2	3	1	3	3	1	YES		
							Summary													
					20/01/92			MOUTH DRY	Detail	7			2	2	3	1	3	3	3	
									Detail	14			2	2	3	1	3	3	3	
									Detail	21			1	2	3	1	3	3	3	
									Detail	28			1	2	3	1	3	3	3	
									Detail	35			1	2	3	1	3	3	3	
									Detail	42			1	2	3	1	3	3	3	
									Summary											
									Summary	42	24/02/92(*)	42	2	2	2	1	3	3	3	3
508	Reboretine				22/01/92	TREMOR	Detail	14			1	2	3	1	3	3	3			
							Detail	21	28/01/92	21	1	2	3	1	3	3	3	1	YES	
							Summary													
							Summary	21												
509	Placebo				19/02/92	MOUTH DRY	Detail	21			1	2	3	1	3	3	3			
							Detail	28			1	3	1	3	3	3	3			
							Detail	35			1	3	1	3	3	3	3			
							Detail	42	11/02/92	42	1	2	3	1	3	3	3	1	YES	
						Summary														
						Summary	42													
510	Reboretine				10/02/92	MYDRIASIS	Detail	21			2	2	3	1	3	3	3			
							Detail	28			1	2	3	1	3	3	3			
							Detail	35	25/02/92	35	2	2	3	1	3	3	3	1	YES	
							Summary													
						Summary	35													
510	Reboretine				02/03/92		Detail	7			2	2	2	1	3	3	3			
							Detail	14			2	2	3	1	3	3	3	Y		
							Summary													
							Summary	14	11/02/92(*)	14	2	2	2	3	3	1	3	3	Y	
510	Reboretine				04/03/92	INSOMNIA	Detail	14			3	2	3	3	3	1	3	3	Y	
							Summary													
							Summary	14	11/02/92(*)	14	3	2	3	3	3	1	3	3	Y	
							Detail	14												
510	Reboretine				04/03/92	VERTIGO	Detail	14			3	2	3	3	3	1	3	3	Y	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (a) onset date missing; first report visit date used

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

51

9550082

PHARMACIA CNS R&D

REBONETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report date	Saves	Hist	Rel	Stud	Samp	Dis	Re	Out	Still	Disse	Present (C)	
																					visit
5/3	510	Reboxetine	27/02/92	18/03/92	VERTIGO	04/03/92	Summary	11/03/92(*)	14	3	2	3	3	3	1	3	3	Y	YES		
511	Imipramine	19/03/92	21/06/92	SOMNOLENCE	16/03/92	Detail	7			3	2	3	1	3	3	3	3				
						Detail	14			1	2	3	1	3	3	3	3				
						Detail	21	06/06/92		1	3	1	3	3	3	3	3	1			
						Summary	06/06/92		21	3	2	3	1	3	3	3	3	1			NO
						Detail	35			2	2	4	3	3	1	3	3	Y			
						Summary	22/04/92(*)		35	2	2	4	3	3	1	3	3	Y		YES	
512	Placebo	01/06/92	01/06/92	ANXIETY	01/06/92	Detail	7	01/06/92		3	2	4	3	3	2	3	1				
						Summary	01/06/92		7	3	2	4	3	3	2	3	1				YES
513	Imipramine	13/05/92	23/06/92	MOUTH DRY	14/05/92	Detail	7			2	2	3	1	3	3	3	3				
						Detail	14			1	2	3	1	3	3	3	3				
						Detail	21	01/06/92		1	2	3	1	2	3	3	1				
						Summary	01/06/92		21	2	2	3	1	2	3	3	1				YES
						Detail	7			2	2	3	1	3	3	3	3				
						Detail	14			3	2	3	1	3	3	3	3				
						Detail	21			1	2	3	1	3	3	3	3				
						Summary	23/06/92(*)		42	3	2	3	1	3	3	3	3	Y			YES
7/92	101	Reboxetine	27/01/92	08/03/92	MOUTH DRY	02/03/92	Detail	09/03/92		1	3	3	1	2	3	3	1				YES
						Summary	09/03/92		42	1	3	3	1	2	3	3	1				
102	Placebo	23/11/91	03/01/92	RHINITIS	06/12/91	Detail	21	12/12/91		1	1	6	1	2	3	3	1				YES
						Summary	12/12/91		21	1	1	6	1	2	3	3	1				
103	Imipramine	02/01/92	18/01/92	ABDOMINAL PAIN	19/01/92	Detail	21			2	2	6	3	2	1	3	3	Y			YES
						Summary	22/01/92(*)		21	2	2	6	3	2	1	3	3	Y			YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. later.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=uncertain, 5=none
 Symptomatic treatment: 0=none, 1=yes
 (C) adverse event used for statistical analysis
 (H) adverse event still present and date = visit date
 (D) onset date missing: first report visit date used
 (E) onset date missing: start treatment date of report visit

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 17.0
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment		Onset date	Adverse event	End date	Type record	Visit No	Last report visit	Simp	Drug	Hosp	App.	Some	Present	(C)																																																																																
		Start date	End date																																																																																													
7/92	183	Imipramine	92/01/92	18/01/92	AGITATION		Detail	14	22/01/92(*)	14	2	2	5	1	2	3	3	3	Y	YES																																																																												
																					Summary	14	2	2	5	1	2	3	3	3	Y																																																																	
																					COLITIS	18/01/92	Summary	21	22/01/92(*)	21	2	2	5	3	2	1	3	3	Y	YES																																																												
																																					Summary	21	2	2	5	3	2	1	3	3	Y																																																	
																																					DYSPHAGIA	04/01/92	Detail	7		2	2	5	1	2	3	3	3	Y	YES																																													
																																																				Summary	21	2	2	5	3	2	1	3	3	Y																																		
																																																				PARAESTHESIA	09/01/92	Detail	14	22/01/92(*)	14	3	2	5	1	2	3	3	Y	YES																														
																																																																			Summary	14	3	2	5	1	2	3	3	3	Y																			
																																																																			RIGORS	10/01/92	Detail	14	22/01/92(*)	14	2	2	5	1	2	3	3	Y	YES															
																																																																																		Summary	14	2	2	5	1	2	3	3	3	Y				
																																																																																		SWEATING INCREASED	02/01/92	Detail	7		3	2	3	1	2	3	3	3	Y	YES
TINNITUS	10/01/92	Detail	14	22/01/92(*)	14	2	2	1	3	2	1	3	Y	YES																																																																																		
															Summary	21	2	2	1	3																																																																												
															TREMOR	02/01/92	Detail	7	22/01/92(*)	7	2	3	5	1	2	3	3	Y	YES																																																																			
																														Summary	7	2	3	5	1	2																																																												
																														185	Reboxetine	10/04/92	05/05/92	EPIDIDYMITIS		Detail	7	99	13/05/92	99	2	2	6	1	2	3	3	3	Y																																															
																																																		Summary	7																																													

Severity: B=unknown, L=mild, S=severe, -- History: I=present before, 2=not observe bef., S=unknown
 Study drug: I=no change, 2=dose reduced, 3=def. withdrawal, 4=comp. inter.
 Hospital: I=required, 2=not req., 3=not appl.
 Disapp./Reapp.: I=app., 2=not appl.
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present end date = visit date
 (a) onset date missing: first report visit date used
 (b) onset date missing: start treatment date of report visit

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53

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PHARMACIA CNS 280

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit End No data	Last report visit	Save Hist	Rat	Stud Sym	Dis	Re	Out	Skill						
7/02	185	Reboxetine	10/04/92	05/05/92	GAMMA-OT INCREASED	30/04/92	07/05/92(*)	Detail Summary	21	07/05/92(*)	21	2	1	4	1	2	3	3	3	Y	YES		
					IMPOTENCE	12/04/92		Detail Detail Detail Summary	7 26 99	13/05/92 13/05/92		2	2	2	1	2	3	3	3	3	Y	YES	
					URINARY RETENTION	12/04/92		Detail Detail Detail Detail Summary	7 14 26 99	13/05/92 13/05/92		2	2	1	1	1	2	3	3	3	3	Y	YES
185		Placebo	16/04/92	27/05/92	MOUTH DRY	17/04/92		Detail Detail Summary	7 99	30/05/92 30/05/92		1	2	2	1	2	3	3	3	3	3	Y	YES
7/03	190	Reboxetine	28/02/92	09/04/92	FATIGUE	28/02/92		Detail Summary	7	03/03/92 03/03/92		1	2	2	1	3	3	3	3	3	1	YES	
					SUICIDE ATTEMPT	10/04/92		Detail Detail Summary	42 99	15/06/92 15/06/92		3	3	6	3	1	1	3	3	3	3	Y	YES
7/04	193	Placebo	25/01/92	05/03/92	MOUTH DRY	27/01/92		Detail Summary	7	30/01/92 30/01/92		1	2	1	1	3	3	3	3	3	1	YES	YES
					MOUTH DRY	30/01/92		Detail Summary	7	31/01/92 31/01/92		1	2	1	1	3	3	3	3	3	1	YES	YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl.
Disapp./Reapp.: 1=no, 2=yes, 3=not appl.
Symptomatic treatment: 0=no, 1=yes
(*) adverse event used for statistical analysis
(S) onset date missing; first report visit date used
(B) onset date missing; start treatment date of report visit

--- History: 1=represent before, 2=not observe bef., 3=unknown
--- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
--- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none

1590

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54

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REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit No	End date	Last report	Save	Hist	Pal	Stud	Sym	Dis	Re	Out	Still	Appr.	Comp	Present	(C)		
																									Centre	Patient
7/94	187	Imipramine	01/02/92	13/03/92	MOUTH DRY	03/02/92	Detail	7	06/02/92	7	06/02/92	1	2	1	1	3	3	3	1							YES
							Summary	28	27/02/92	28	27/02/92	1	2	1	1	2	3	3	1							YES
							Summary	28	27/02/92	28	27/02/92	26	1	2	2	1	2	3	3	1						YES
189		Imipramine	26/02/92	08/05/92	MOUTH DRY	06/04/92	Detail	14	10/04/92	14	10/04/92	1	2	3	1	2	3	3	1							YES
							Summary	19	06/04/92	19	06/04/92	14	1	2	3	1	2	3	5	1						YES
201		Reboxetine	28/05/92	08/05/92	HEADACHE	19/04/92	Detail	26	20/04/92	26	20/04/92	1	1	3	1	2	3	3	1							YES
							Summary	20	04/92	20	04/92	26	1	1	3	1	2	3	3	1						YES
284		Imipramine	04/04/92	15/05/92	MOUTH DRY	19/04/92	Detail	21	23/04/92	21	23/04/92	1	2	3	1	2	3	3	1							YES
							Summary	23	04/92	23	04/92	21	1	2	3	1	2	3	3	1						YES
7/05	207	Imipramine	28/01/92	09/03/92	MOUTH DRY	23/02/92	Detail	28	02/03/92	28	02/03/92	1	3	3	1	3	3	3	1							YES
							Summary	24	02/92	24	02/92	26	1	3	3	1	3	3	3	1						YES
289		Placebo	05/02/92	17/03/92	NAUSEA	02/03/92	Detail	28	02/03/92	28	02/03/92	1	3	3	1	3	3	3	1							YES
							Summary	02	03/92	02	03/92	26	1	3	3	1	3	3	5	1						YES
542		Imipramine	17/03/92	27/04/92	VOMITING	20/03/92	Detail	7	31/03/92	7	31/03/92	1	3	3	1	3	3	3	1							YES
							Summary	21	03/92	21	03/92	7	1	3	3	1	3	3	5	1						YES
543		Imipramine	18/03/92	28/04/92	MOUTH DRY	26/03/92	Detail	14	27/03/92	14	27/03/92	1	1	3	1	3	3	3	1							YES
							Summary	27	03/92	27	03/92	14	1	1	3	1	3	3	3	1						YES
7/07	529	Placebo	18/02/92	31/05/92	NAUSEA	07/03/92	Detail	21		21		2	2	1	1	2	3	3	3							YES
							Detail	26	19/03/92	26	19/03/92	1	2	5	1	3	3	3	1							YES
							Summary	19	03/92	19	03/92	26	2	2	2	1	2	3	3	1						YES
						SWEATING INCREASED	Detail	14		14		2	2	2	1	2	3	3	3							YES
							Detail	21		21		2	2	3	1	2	3	3	3							YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=stop, 4=intermittent, 5=stop, 6=withdrawn, 7=stop, 8=intermittent,
Hospital: 1=required, 2=not req., 3=not appl., -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl., -- Relationship: 1=definite, 2=probable, 3=possible, 4=suspect, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(*) adverse event used for statistical analysis
(**) adverse event still present: end date = visit date
(***) onset date missing: first report visit date used
(****) onset date missing: start treatment date of report visit

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55

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REBOXETINE - PROTOCOL 20124/ALS
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Last report save	Hist	Rel	Stud	Symp	Dis	Re	Out	Still		
			Start date	End date													
7/07	529	Placebo	18/02/92	31/03/92	24/02/92	SWEATING INCREASED	26	2	2	1	1	3	3	3	Y		
							Summary	31/03/92(*)	26	2	2	1	1	2	3	Y	
					07/03/92	VOMITING											
							Detail	21 18/03/92	2	2	4	1	2	3	3	1	
							Summary	18/03/92	21	2	2	4	1	2	3	3	1
					21/02/92	ABDOMINAL PAIN											
							Detail	7 24/02/92	1	2	4	1	3	3	3	1	
							Summary	24/02/92	7	1	2	4	1	3	3	3	1
					21/02/92												
							Detail	14	2	2	3	1	2	3	3	3	
							Detail	21 09/03/92	1	2	5	1	2	3	3	1	
							Summary	09/03/92	21	2	2	3	1	2	3	3	1
					24/02/92	CHEST PAIN											
							Detail	7 28/02/92	1	2	2	1	3	3	3	1	
							Summary	28/02/92	7	1	2	2	1	3	3	3	1
					21/02/92	CHEST PAIN PRECORDIAL											
							Detail	7	1	2	2	1	2	3	3	3	
							Detail	21 09/03/92	1	2	1	1	2	3	3	1	
							Summary	09/03/92	21	1	2	2	1	2	3	3	1
					21/02/92	SWEATING INCREASED											
							Detail	7	2	2	3	1	2	3	3	3	
							Detail	14 03/03/92	3	2	1	3	2	2	1	1	
							Summary	03/03/92	14	3	2	1	3	2	2	1	1
					18/05/92												
							Detail	21	2	1	5	1	2	3	3	3	
							Detail	28 21/05/92	2	1	5	1	2	3	3	1	
							Summary	21/05/92	28	2	1	5	1	2	3	3	1
					01/05/92												
							Detail	7	1	2	2	1	2	3	3	3	
							Detail	14 14/05/92	1	2	2	1	2	3	3	1	
							Summary	14/05/92	14	1	2	2	1	2	3	3	1
					25/11/91	SUICIDE ATTEMPT											
							Detail	7 25/11/91	6	1	3	3	3	3	4	Y	
							Summary	25/11/91	7	6	1	3	3	3	4	Y	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=none, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Respp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (e) adverse event still present; end date = visit date
 (d) onset date missing; first report visit date used
 (f) onset date missing; start treatment date at report visit

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 201247015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre Patient	Drug	Treatment		Onset date	Adverse event	Type	Visit No	End date	Lact report	Sae	Hist	Rel	Stud	Symp	Dis	Re	Out	Still											
		Start date	End date																										
0	233	Placebo	07/10/92	17/11/92	CONSTIPATION		14	20/10/92	14	1	1	4	1	2	3	3	1	YES											
			Summary	20/10/92															14	1	1	4	1	2	3	3	1		
8/A	237	Reboxetine	14/10/92	24/11/92	VISION ABNORMAL		7	18/10/92	7	1	2	4	1	2	3	3	1	YES											
			Summary	18/10/92															7	1	2	4	1	2	3	3	1		
5/S	Reboxetine	14/10/92	20/11/92	ASTHENIA		7	21/10/92	7	2	1	3	1	2	3	3	1	YES												
																		Summary	21/10/92	7	2	1	3	1	2	3	3	1	
9	241	Placebo	07/02/91	17/02/91	AGITATION		7	10/02/91(*)	14	3	2	3	1	3	3	3	3	3	Y										
			Summary	10/02/91(*)																14	3	2	3	3	3	3	3	3	
			Detail	14																3	2	3	3	3	3	3	3	3	
			Detail	7																2	2	3	1	3	3	3	3	3	
242	Reboxetine	14/02/91	11/03/91	CONSTIPATION		7	18/02/91(*)	14	5	2	3	5	3	3	3	3	3	Y											
																			Summary	18/02/91(*)	14	5	2	3	5	3	3	3	3
																			Detail	14	5	2	3	1	3	3	3	3	3
																			Detail	7	2	2	3	1	3	3	3	3	3
243	Reboxetine	16/02/91	11/03/91	CONSTIPATION		7	11/03/91(*)	7	2	1	4	1	3	3	3	3	3	Y											
																			Summary	11/03/91(*)	7	2	1	4	1	3	3	3	3
																			Detail	14	3	1	4	1	4	1	3	3	3
																			Detail	21	3	1	4	1	4	1	3	3	3
244	Reboxetine	11/03/91	11/03/91	CONSTIPATION		21	11/03/91(*)	21	5	1	4	1	4	5	5	3	3	Y											
																			Summary	11/03/91(*)	21	5	1	4	1	4	5	5	3
																			Detail	14	5	1	4	1	4	1	4	5	3
																			Detail	21	2	1	4	1	4	1	3	3	3
245	Reboxetine	11/03/91	11/03/91	CONSTIPATION		21	11/03/91(*)	21	2	1	4	1	3	3	3	3	3	Y											
																			Summary	11/03/91(*)	21	2	1	4	1	3	3	3	3
																			Detail	14	2	1	4	1	4	1	3	3	3
																			Detail	21	2	1	4	1	4	1	3	3	3
246	Reboxetine	11/03/91	11/03/91	VERTIGO		7	25/02/91	7	1	1	4	1	3	3	3	3	1	YES											
																			Summary	25/02/91	7	1	1	4	1	3	3	3	1
																			Detail	14	1	1	4	1	4	1	3	3	1
																			Detail	21	1	1	4	1	4	1	3	3	1

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe;
Study drug: 1=no change, 2=dose reduced, 3=dof. withdrawn, 4=stop. later.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rel. with see., 3=still present, 4=death
Disapp./Rapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=unclear, 5=unknown, 6=nona
Symptomatic treatment: 0=no, 1=yes
(*) adverse event used for statistical analysis
(†) adverse event still present: end date = visit date
(‡) onset date missing: first report visit date used
(§) onset date missing: start treatment date of report visit

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5/

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/D15
 Listing No.: 17.0
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit	Last report	Save	Hist	Rel	Stud	Symp	Dis	Rx	Out	Still													
										visit	city	dry	ship	drug	trns	Hosp	app.	app.	coma	present	(C)											
9	243	Reboxetine	20/02/91	06/03/91	AGITATION		26/02/91	Detail	7																							
								Detail	14																							
								Summary		06/03/91(*)	14	5	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y			
								Detail	7																							
								Detail	14																							
								Summary		06/03/91(*)	14	5	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	Y		
	244	Imipramine	19/02/91	13/03/91	CONJUNCTIVITIS			25/02/91	Detail	7																						
									Detail	14																						
									Summary		06/03/91(*)	14	3	2	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y		
									Detail	7																						
									Detail	14																						
									Summary		06/03/91(*)	14	3	2	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	Y	
245	Imipramine	22/02/91	04/04/91	DIZZINESS			22/02/91	Detail	7																							
								Detail	14																							
								Summary		13/03/91(*)	14	2	1	5	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y			
								Detail	7																							
								Detail	14																							
								Summary		06/03/91	14	1	2	5	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	1	Y	
245	Imipramine	22/02/91	04/04/91	DIZZINESS			27/02/91	Detail	14																							
								Summary		13/03/91(*)	14	2	1	5	1	3	3	3	3	3	3	3	3	3	3	3	3	Y				
								Detail	21																							
								Summary		13/03/91(*)	21	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	Y		
								Detail	7																							
								Summary		13/03/91(*)	21	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	Y		
245	Imipramine	22/02/91	04/04/91	DIZZINESS			11/03/91	Detail	7																							
								Detail	21																							
								Summary		13/03/91(*)	21	2	3	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y			
								Detail	7																							
								Detail	21																							
								Summary		13/03/91(*)	21	2	3	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	Y		
245	Imipramine	22/02/91	04/04/91	DIZZINESS			19/03/91	Detail	21																							
								Detail	28																							
								Summary		17/03/91	28	1	2	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	1	Y		
								Detail	21																							
								Detail	28																							
								Summary		17/03/91	28	1	2	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	1	Y	
245	Imipramine	22/02/91	04/04/91	DIZZINESS			03/04/91	Detail	42																							
								Summary		03/04/91	42	1	2	6	1	2	3	3	3	3	3	3	3	3	3	3	3	Y				

Severely: 0=unknown, 1=mild, 2=moderate, 3=severe,
 Study drug: 1=one change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.,
 Hospital: 1=requir'd, 2=not req'd, 3=not appl., --- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./reapp.: 1=no, 2=yes, 3=not appl., --- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (P) adverse event still present; end date = visit date
 (D) onset date missing; first report visit date used
 (S) onset date missing; start treatment date of report visit

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56

PHARMACIA CNS R&D

REBONETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment		Onset date	Type	Visit No	Last report date	Hit	Rel	Stud Sym	Dis	Re	Out	Still						
		Start date	End date												Adverse event	visit	city	ary	ship	drug
9	245	Imipramine	22/02/91	06/06/91	NAUSEA	Summary	05/04/91(*)	42	1	2	4	1	2	3	3	3	3	Y	YES	
	246	Placebo	22/02/91	17/03/91	BRODYCARDIA	Detail Summary	18/03/91 18/03/91	3 28	2	2	3	3	2	2	3	2	3	1	YES	
	247	Placebo	25/02/91	24/03/91	NAUSEA	Detail Detail Summary	21 28 24/03/91	1 1 28	2	4	1	3	3	3	3	3	3	1	YES	
	248	Placebo	07/02/91	21/03/91	AGITATION	Detail Summary	14 22/03/91(*)	3 14	2	2	3	3	2	3	2	3	2	3	Y	YES
	250	Imipramine	12/03/91	08/04/91	CONSTIPATION	Detail Summary	8 08/04/91(*)	0											NO	
				01/04/91	DYSPEPSIA	Detail Summary	21 02/04/91	1 21	3	5	1	3	3	3	1	3	3	1	YES	
				01/04/91	NAUSEA	Detail Summary	21 02/04/91	2 21	3	5	1	3	3	3	1	3	3	1	YES	
	251	Imipramine	22/03/91	12/04/91	MOUTH DRY	Detail Detail Detail Detail Summary	7 14 21 28 12/04/91(*)	2 2 2 2 28	2	2	3	1	3	3	3	3	3	3	Y	YES
				23/02/91	TREMOR	Detail Detail Detail Detail Summary	7 14 21 28 12/04/91(*)	2 2 2 2 28	2	2	3	1	3	3	3	3	3	3	Y	YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=stop later.
Hospital: 1=required, 2=not req., 3=not appl. --- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Resp.: 1=no, 2=yes, 3=not appl. --- Relationship: 1=definite, 2=probable, 3=possible, 4=suspected, 5=unknown, 6=none
(C) adverse event used for statistical analysis
(*) adverse event still present and date = visit date
(S) onset date missing; first report visit date used
(B) onset date missing; start treatment date of report visit

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51

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PHARMACIA CNS R&D

REMEXETINE - PROTOCOL 20124/015
Listing No.: 17, P

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End No date	Last report visit	Sae	Hst	Rel	Stud	Symp	Dis app.	Re app.	Out	Skill	Comp	Present	(c)																																																													
																							city	dry	ship	traf	Hosp	app.	app.	comp	Present	(c)																																																			
9	252	Remexetine	02/06/91	28/06/91	AGITATION	10/06/91	Detail	16																																																																											
																								3	2	3	1	3	3	3	3	3	3	Y																																																	
																								21	3	2	3	2	3	1	3	3	3	Y																																																	
																								Summary	20/06/91(*)	21	3	2	3	2	3	1	3	3	Y																																																
																								253	Remexetine	02/06/91	08/06/91	HEADACHE	08/06/91	Detail	7	10/06/91																																																			
																																																2	1	4	1	3	3	3	1																												
																																																14	10/06/91	2	1	4	1	3	3	3	1																										
																																																Summary	10/06/91	14	2	1	4	1	3	3	3	1	YES																								
																																																254	Remexetine	02/06/91	08/06/91	MOUTH DRY	10/06/91	Detail	14																												
																																																																								1	2	4	1	3	3	3	3	3	3	Y	
																																																																								21	1	2	3	2	3	1	3	3	3	Y	
																																																																								Summary	28/06/91(*)	21	1	2	3	2	3	1	3	3	Y
255	Remexetine	02/06/91	08/06/91	MUSCLE CONTRACTIONS INVOL	15/06/91	Detail	21																																																																												
																																																																								2	2	3	2	3	1	3	3	3	Y		
																																																																								21	2	2	3	2	3	1	3	3	3	Y	
																																																																								Summary	28/06/91(*)	21	2	2	3	2	3	1	3	3	Y
																								255	Remexetine	02/06/91	08/06/91	TREMOR	10/06/91	Detail	14																																																				
																																																																								1	2	4	1	3	3	3	3	3	Y		
																																																																								21	1	2	3	2	3	1	3	3	3	Y	
																																																																								Summary	28/06/91(*)	21	1	2	3	2	3	1	3	3	Y
																																																255	Remexetine	02/06/91	08/06/91	AGITATION	08/06/91	Detail	7																												
																																																																								3	2	3	3	3	2	3	3	3	3	Y	
																																																																								7	3	2	3	3	3	2	3	3	3	Y	
																																																																								Summary	08/06/91(*)	7	3	2	3	3	3	2	3	3	Y
254	Imipramine	07/06/91	16/06/91	INSOMNIA	10/06/91	Detail	7																																																																												
																																																																								3	1	3	1	YES	3	3	3	3	3	Y	
																																																																								14	3	1	3	3	3	3	3	3	3	Y	
																																																																								Summary	17/06/91(*)	14	3	1	3	3	YES	3	3	3	Y
																								254	Imipramine	07/06/91	16/06/91	MOUTH DRY	10/06/91	Detail	7																																																				
																																																																								2	2	3	1	3	3	3	3	3	3	Y	
																																																																								14	2	2	3	3	3	3	3	3	3	Y	
																																																																								Summary	17/06/91(*)	14	2	2	3	3	3	3	3	3	Y
																																																254	Imipramine	07/06/91	16/06/91	TREMOR	10/06/91	Detail	6																												
																																																																								2											

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=coef. withdrawn, 4=stop. inter.
 Hospital: 1=required, 2=not req., 3=not appl.
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl.
 Symptomatic treatment: 1=no, 2=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (S) onset date missing; first report visit date used
 (E) onset date missing; start treatment date of report visit

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

60

9550082

PHARMACIA CNS RED
 REBONETINE - PROTOCOL 2013/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Address event	Onset date	Type record	Visit No	End date	List report visit	Save Hist	Rel. Ship	Stud. app.	Simp.	Dis. app.	Re. app.	Out. app.	Still Present (C)				
																			report	visit	save	hist
254	Imipramine	09/04/91 - 11/04/91	TREMOR	09/04/91	11/04/91	17/04/91(*)	Summary	7	17/04/91(*)	9	2	3	1	3	1	3	3	3	NO			
				17/04/91	Detail	7	3	1	3	1	3	3	3	3	3	3	3	3	3	3	3	
				17/04/91	Detail	14	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y
				17/04/91	Summary	14	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y
				21/05/91	Detail	14	3	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
				21/05/91	Detail	21	3	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
				06/06/91	Detail	26	3	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
				06/06/91	Summary	26	3	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
				23/05/91	Detail	14	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	Y
				06/06/91	Summary	21	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	1
255	Rebonetine	13/05/91 - 06/06/91	AGITATION	21/05/91	06/06/91	06/06/91(*)	Detail	14	06/06/91(*)	26	2	2	3	1	3	3	3	3	Y			
				06/06/91	Detail	14	3	2	3	1	3	3	3	3	3	3	3	3	3	3	Y	
				06/06/91	Detail	21	3	2	3	1	3	3	3	3	3	3	3	3	3	3	Y	
				06/06/91	Detail	26	3	2	3	1	3	3	3	3	3	3	3	3	3	3	Y	
				06/06/91	Summary	26	3	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
				21/05/91	Detail	26	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
				06/06/91	Summary	26	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
				24/05/91	Detail	14	1	2	4	1	3	3	3	3	3	3	3	3	3	3	3	Y
				06/06/91	Detail	26	1	2	4	1	3	3	3	3	3	3	3	3	3	3	3	Y
				06/06/91	Summary	26	1	2	4	1	3	3	3	3	3	3	3	3	3	3	3	Y
256	Imipramine	27/05/91 - 08/07/91	CONSTIPATION	08/07/91	08/07/91	08/07/91(*)	Detail	26	08/07/91(*)	20	1	3	6	1	3	3	3	3	Y			
				08/07/91	Detail	26	1	3	6	1	3	3	3	3	3	3	3	3	3	3	Y	
				08/07/91	Summary	26	1	3	6	1	3	3	3	3	3	3	3	3	3	3	Y	
				26/06/91	Detail	35	2	1	3	2	YES	3	3	3	3	3	3	3	3	3	3	Y
				08/07/91	Detail	42	2	1	3	2	YES	3	1	3	3	3	3	3	3	3	3	Y
				08/07/91	Summary	42	2	1	3	2	YES	3	1	3	3	3	3	3	3	3	3	Y
				01/07/91	Detail	35	2	3	5	2	YES	3	3	3	3	3	3	3	3	3	3	Y
				01/07/91	Detail	42	2	3	5	2	YES	3	3	3	3	3	3	3	3	3	3	Y
				01/07/91	Summary	42	2	3	5	2	YES	3	3	3	3	3	3	3	3	3	3	Y

Severity: 1=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=stop, 4=withdrawn, 5=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=None
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (S) adverse event still present; end date = visit date
 (D) onset date missing; first report visit date used
 (B) onset date missing; start treatment date of report visit

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41

9550082

PHARMACIA CNS RED

REBOMETINE - PROTOCOL 2012/0115
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit	End No data	Last report	Sae	Hst	Rel	Stud	Sym	Dis	Re	Dut	Skill	app.	Some	Present	(C)	
																							report
9	256	Imipramine	27/05/91	08/07/91	INSPEPSIA	01/07/91	Summary	08/07/91(*)	42	2	3	5	2	YES	3	3	3	3	3	3	Y	YES	
				HYPOENSION	04/06/91	Detail	14	04/06/91	1	2	3	1			3	3	3	3	1			YES	
					04/06/91	Summary	14	04/06/91	1	2	3	1			3	3	3	3	1				YES
				HYPOENSION POSTURAL	01/07/91	Detail	35		2	3	3	2	YES	3	3	3	3	3	3	3	Y	YES	
					01/07/91	Detail	42		2	3	3	2	YES	3	3	3	3	3	3	3	Y	YES	
					08/07/91(*)	Summary	42	08/07/91(*)	42	2	3	3	2	YES	3	3	3	3	3	3	Y	YES	
				INSOMNIA	24/05/91	Detail	7		2	1	4	1	YES	3	3	3	3	3	3	3	Y	YES	
					24/05/91	Detail	26		3	2	3	2	YES	3	3	3	3	3	3	3	Y	YES	
					24/05/91	Detail	42		2	1	4	2	YES	3	3	3	3	3	3	3	Y	YES	
					08/07/91(*)	Summary	42	08/07/91(*)	42	3	1	3	2	YES	3	1	3	3	3	3	Y	YES	
				MOUTH DRY	29/05/91	Detail	7		2	2	3	1			2	3	3	3	3	3	Y	YES	
					29/05/91	Detail	42		2	2	3	2			2	1	3	3	3	3	Y	YES	
					08/07/91(*)	Summary	42	08/07/91(*)	42	2	2	3	2		2	1	3	3	3	3	Y	YES	
				SWEATING INCREASED	29/05/91	Detail	7		1	2	3	1			3	3	3	3	3	3	Y	YES	
					29/05/91	Detail	42	04/06/91	1	2	3	1			3	3	3	3	3	3	1		YES
					04/06/91	Summary	42	04/06/91	42	1	2	3	1		3	3	3	3	3	3	1		YES
				TREMOR	04/06/91	Detail	14		3	2	2	2			3	2	3	3	3	3	Y	YES	
					04/06/91	Detail	21		1	2	3	2			3	2	3	3	3	3	Y	YES	
					04/06/91	Detail	28		2	2	2	2			3	2	2	3	3	3	Y	YES	
					04/06/91	Detail	42		3	2	2	1			3	3	3	3	3	3	Y	YES	
					08/07/91(*)	Summary	42	08/07/91(*)	42	3	2	2	2		3	3	3	3	3	3	Y	YES	
11	258	Placebo	01/07/91	10/07/91	AGITATION	02/07/91	Detail	7		1	2	4	1		3	3	3	3	3	3	Y	YES	
					02/07/91	Detail	14		1	2	4	1			3	3	3	3	3	3	Y	YES	
					10/07/91(*)	Summary	14	10/07/91(*)	14	1	2	4	1		3	3	3	3	3	3	Y	YES	
				AMOREXIA	02/08/91	12/09/91	Detail	0		1													

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=discontinued, 4=withdrawn, 5=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present; end date = visit date
(S) onset date missing; first report visit date used
(E) onset date missing; start treatment date of report visit

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52

9550082

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 28124/015
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit No	End date	LAST	Report	Sae	Hist	Rel	Stud	Syst	Dis	Re	Out	Skill	Present	(C)		
																							visit	city
11	319	Placebo	02/06/91	12/09/91	ANOREXIA	24/07/91	(C)	Summary	12/09/91	(*)	0	1											NO	
					INSOMNIA	24/07/91	(C)	Summary	12/09/91	(*)	0	2											NO	
						07/08/91	(C)	Summary	26/09/91	(*)	0	1											NO	
					CONSTIPATION	18/08/91		Summary	26/09/91	(*)	7	1	2	2	1	2	3	3	3	3	3	3	Y	YES
					DIZZINESS	25/08/91		Summary	30/08/91		2	2	2	2	1	2	3	3	3	3	3	3	Y	YES
					INSOMNIA	07/08/91	(C)	Summary	26/09/91	(*)	0	3											NO	
					MOUTH DRY	18/08/91		Summary	26/09/91	(*)	7	1	2	2	1	2	3	3	3	3	3	3	Y	YES
					SWEATING INCREASED	07/08/91	(C)	Summary	26/09/91	(*)	0	1											NO	
					CONSTIPATION	18/09/91		Summary	17/10/91	(*)	21	1	2	2	1	2	3	3	3	3	3	3	Y	YES
					VISION ABNORMAL	15/09/91		Summary	17/10/91	(*)	14	1	2	2	1	2	3	3	3	3	3	3	Y	YES
					CONSTIPATION	27/09/91		Summary	26/09/91	(*)	2	2	2	1	2	3	3	3	3	3	3	3	Y	YES

Sever-ity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=stop. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=err. with sac, 3=still present, 4=deach
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4= doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(D) onset date missing: first report visit date used
(S) onset date missing: start treatment date of report visit

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

63

9550082

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report	Sae	Hist	Rel	Stud	Symp	Dis	Re	Out	Skill	Some present (c)		
																					report	visi
11	322	Reboxetine	27/09/91	07/11/91	CONSTIPATION	28/09/91	Summary		07/11/91	11*	7	2	2	2	1	2	3	3	3	3	Y	YES
					INSOMNIA	01/11/91	Detail	42	04/11/91							YES						YES
						05/11/91	Summary		05/11/91	42						YES						YES
					VISION ABNORMAL	01/10/91	Detail	14	12/10/91		1	2	2	1		2	3	3	1			YES
						12/10/91	Summary		12/10/91	14	1	2	2	1		2	3	3	1			YES
	325	Reboxetine	15/11/91	26/12/91	MYOCLIASIS	15/11/91	Detail	7	19/11/91		1	2	3	1		2	3	3	1			YES
						19/11/91	Summary		19/11/91	7	1	2	3	1		2	3	3	1			YES
					SWEATING INCREASED	18/11/91	Detail	7	08/12/91		1	1	3	1		2	3	3	1			YES
						08/12/91	Summary		08/12/91	7	1	1	3	1		2	3	3	1			YES
	326	Imipramine	06/12/91	16/01/92	CONSTIPATION	20/12/91	Detail	21	20/12/91		1	2	2	1		2	3	3	1			YES
						20/12/91	Summary		20/12/91	21	1	2	2	1		2	3	3	1			YES
					INSOMNIA	05/01/92	Detail	55	06/01/92							YES						YES
						06/01/92	Summary		06/01/92	55						YES						YES
					TREMOR	14/12/91	Detail	14			1	2	3	1		2	3	3	3			Y
						14/12/91	Detail	35														Y
						14/12/91	Detail	42														Y
						15/01/92	Summary		15/01/92	42	1	2	3	1		2	3	3	3			Y
	327	Imipramine	31/01/92	05/02/92	DIURIA	31/01/92	Detail	7	02/02/92		1	2	3	1		2	3	3	1			YES
						02/02/92	Summary		02/02/92	7	1	2	3	1		2	3	3	1			YES
	328	Imipramine	31/01/92	04/02/92	VERTIGO	02/02/92	Detail	7	04/02/92		2	2	2	1		2	3	3	1			YES
						04/02/92	Summary		04/02/92	7	2	2	2	1		2	3	3	1			YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
Study drug: 1=no change, 2=dose reduced, 3=dis. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=dech
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present; end date = visit date
(D) onset date missing; first report visit date used
(E) onset date missing; start treatment date of report visit

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

64

9550082

PHARMACIA CMS R&D

REBOXETINE - PROTOCOL 20126/915
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report										
											Sev	Rel	Stud	Symp	Dis	Ra	Out	Still	Present	(c)	
11	329	Placebo	18/04/92	21/05/92	ABDOMINAL PAIN	15/04/92	Detail	7	18/04/92	7	18/04/92	2	2	3	1	2	3	3	1	YES	
							Summary	18/04/92	7	2	2	3	1	2	3	3	1				
330	Reboxetine	09/04/92	21/05/92	MOUTH DRY	11/04/92	Detail	7	29/04/92	1	2	2	1	2	3	3	1				YES	
							Summary	29/04/92	7	1	2	2	1	2	3	3	1				
331	Imipramine	17/04/92	20/05/92	SOMNOLENCE	17/04/92	Detail	7	20/05/92(*)	1	2	2	1	2	3	3	3	3	3	Y	YES	
							Summary	20/05/92(*)	7	1	2	2	1	2	3	3	3	3	Y		
332	Reboxetine	11/05/92	21/05/92	MOUTH DRY	23/05/92	Detail	7	03/06/92	1	2	2	1	2	3	3	1				YES	
							Summary	03/06/92	7	1	2	2	1	2	3	3	1				
333	Placebo	27/05/92	07/07/92	RHINITIS	28/05/92	Detail	7	02/06/92	1	1	4	1	2	3	3	1				YES	
							Summary	02/06/92	7	1	1	4	1	2	3	3	1				
334	Reboxetine	29/05/92	31/05/92	CHEST PAIN	17/06/92	Detail	28	25/06/92	1	2	2	1	2	3	3	1				YES	
							Summary	25/06/92	28	1	2	2	1	2	3	3	1				
						SOMNOLENCE															
							Detail	7	01/06/92(*)	3	1	2	3	2	3	3	Y			YES	
							Summary	01/06/92(*)	7	3	1	2	3	2	2	3	3	Y			
						DIZZINESS	29/05/92	Detail	7	01/06/92(*)	2	2	2	3	2	3	3	Y		YES	
							Summary	01/06/92(*)	7	2	2	2	3	2	2	3	3	Y			
						PARAESTHESIA	29/05/92	Detail	7	01/06/92(*)	2	2	3	2	2	3	3	Y		YES	
							Summary	01/06/92(*)	7	2	2	3	2	2	3	3	Y				
						SWEATING INCREASED	29/05/92	Detail	7	01/06/92(*)	2	1	2	3	2	3	3	Y		YES	
							Summary	01/06/92(*)	7	2	1	2	3	2	2	3	3	Y			
337	Reboxetine	02/07/92	13/08/92	MOUTH DRY	03/07/92	Detail	7	30/07/92	1	2	2	1	2	3	3	1				YES	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=temp. lower
 Hospital: 1=required, 2=not req., 3=not appl.
 Disapp./Resp.: 1=no, 2=yes, 3=not appl.
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (S) onset date missing; first report visit date used
 (E) onset date missing; start treatment date of report visit

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

65

9550082

PHARMACIA CNS RED

REBEXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report date	Risky	Study	Drug	Dose	Present	C		
																report date	Study
11	337	Rebexetine	02/07/92	13/08/92	MOUTH DRY	03/07/92	Summary	7	1 2 2 1		2	3	3	1	YES		
12	347	Rebexetine	20/12/91	30/01/92	MOUTH DRY	19/12/91	Detail 6	1									
							Detail 7	1	1	4	1	3	3	3			
							Detail 14	2	1	1	1	3	3	3			
							Detail 21	2	4	1	1	2	3	3			
							Detail 28	2	1	1	1	2	3	3			
						31/01/92	Detail 55	1	1	4	1	2	3	3			
							Detail 42	1	1	4	1	2	3	3			
							Detail 42	1	1	4	1	2	3	3			
							Summary	42	2	1	1	2	3	3			
							Summary	31/01/92	42	2	1	1	2	3	3		
348	Placebo	24/12/91	03/02/92	CHEST PAIN PRECORDIAL	05/01/92	Detail 14	1	2	4	1	YES	3	3	3	1	YES	
						Summary	14	1	2	4	1	YES	3	3	3	1	YES
					CHROMATOPSIA	13/01/92	Detail 21	1	2	6	1	3	3	3	1	YES	
							Summary	13/01/92	21	1	2	6	1	3	3	3	1
					MOUTH DRY	02/01/92	Detail 14	1	2	4	1	3	3	3	3		
							Detail 21	1	3	3	1	3	3	3	1		
						14/01/92	Summary	21	1	2	3	1	3	3	3	1	YES
							Summary	14/01/92	21	1	2	3	1	3	3	3	1
359	Isipramine	23/06/92	13/05/92	CONSTIPATION	22/04/92	Detail 7	27/06/92	1	1	3	1	2	3	3	1	NO	
						Summary	27/06/92	7	1	1	3	1	2	3	3	1	NO
					DYSPEPSIA	25/04/92	Detail 7	25/04/92	1	2	3	1	3	3	1	YES	
							Summary	25/04/92	7	1	2	3	1	3	3	1	YES
					MOUTH DRY	25/04/92	Detail 7	27/04/92	1	2	2	1	3	3	3	1	YES
							Summary	27/04/92	7	1	2	2	1	3	3	3	1
					SWEATING INCREASED	01/05/92	Detail 14	08/05/92	2	2	4	1	2	3	3	1	YES
							Summary	06/05/92	14	2	2	4	1	2	3	3	1

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=drug withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (Y) adverse event still present: end date = visit date
 (N) onset date missing: first report visit date used
 (M) onset date missing: start treatment date of report visit

1602

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64

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit End No data	Last report save visit rty	Hist ary ship	Rel drug	Stud app.	Symp.	Dis app.	Re	Dut	Still	Present (C)							
																				report save visit rty	Hist ary ship	Rel drug	Stud app.	Symp.	Dis app.	Re
12	376	Placebo	29/06/92	29/05/92	FLUSHING	25/06/92	0	Detail	0	1										NO						
							Summary	20/05/92(*)	0	1																
							HEADACHE	21	13/05/92	2	1	6	1	2	3	3	1									
								Summary	13/05/92	21	2	1	6	1	2	3	3	1								
							MYALGIA	7	29/06/92	1	2	5	1	3	3	3	1									
								Summary	29/06/92	7	1	2	5	1	3	3	3	1								
							OEDEMA LEGS	0	29/05/92(*)	0	1															
								Summary	29/05/92(*)	0	1															
							PALPITATION	21	13/05/92	1	2	6	1	2	3	3	1									
								Summary	13/05/92	21	1	2	6	1	2	3	3	1								
							TREMOR	7	29/06/92	1	2	5	1	3	3	3	1									
								Summary	29/06/92	7	1	2	5	1	3	3	3	1								
URINARY RETENTION	7	29/06/92	1	2	5	1	3	3	3	1																
	Summary	29/06/92	7	1	2	5	1	3	3	3	1									YES						
371	Imipramine	01/05/92	06/05/92	FURUNCULOSIS	16/06/92	0	Detail	0	1											NO						
						Summary	06/05/92(*)	0	1																	
				HEADACHE	17/06/92	0	Detail	0	2											NO						
						Summary	08/05/92(*)	0	2																	
				MOUTH DRY	01/05/92	7	Detail	7	2	2	3	1	3	3	3	3	3	3	3	3	Y					
						Summary	08/05/92(*)	7	2	2	3	1	3	3	3	3	3	3	3	3	3	3	Y			

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe.
 Study drug: 1=no change, 2=dose reduced, 3=stop, 4=withdrawn, 5=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. --- Outcome: 1=recovered, 2=rel. with set., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. --- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (M) adverse event still present and date = visit date
 (D) onset date missing: first report visit date used
 (S) onset date missing: start treatment date of report visit

1603

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67

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit No	End No date	Last report	Save	Hist	Rel	Stud	Sympt	Dis	Re	Out	Still		
12	371	Imipramine	01/05/92	06/05/92	RHINITIS	22/06/92	Detail	0			0	2										
							Summary	08/05/92(*)			0	2									NO	
372	Reboxetine	02/06/92	13/07/92	CONSTIPATION	06/06/92	Detail	7		1	2	3	1									Y	
							Summary	13/07/92(*)		7	1	2	5	1								Y
							Detail	7		2	2	6	1	YES								Y
							Summary	13/07/92(*)		7	2	2	6	1	YES							Y
							Detail	7		2	2	6	1	YES								Y
							Summary	13/07/92(*)		28	2	1	3	1	YES							Y
							Detail	7		2	2	3	1	YES								Y
							Summary	03/06/92		7	3	1	6	1	YES							Y
							Detail	7		7	3	1	6	1	YES							Y
							Summary	03/06/92		7	3	1	6	1	YES							Y
							Detail	7		1	2	3	1									Y
							Summary	13/07/92(*)		7	1	2	3	1								Y
							Detail	7		7	0	5	1	YES								Y
							Summary	03/06/92		7	3	1	6	1	YES							Y
							Detail	7		7	0	5	1	YES								Y
							Summary	03/06/92		7	2	1	6	1	YES							Y
							Detail	7		7	2	1	6	1	YES							Y
							Summary	03/06/92		7	2	1	6	1	YES							Y
							Detail	7		7	0	5	1	YES								Y
							Summary	03/06/92		7	5	1	6	1	YES							Y
373	Reboxetine	05/06/92	14/07/92	CONSTIPATION	09/06/92	Detail	7		1	2	3	1										Y
							Summary	16/07/92(*)		42	1	2	3	1								Y

Severity: 0=unknown, 1=ild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Respp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: none, 1=yes
(c) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(0) onset date missing: first report visit date used
(8) onset date missing: start treatment date of report visit

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16

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PHARMACIA CNS RED
 RESOMETINE - PROTOCOL 20124/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report	Save Hist	Rel ship	Stud Sympt	Dis app.	Re pres	Out Still						
																	visit	orig	drug	tr eat	Hosp app.	app. com
12	373	Resometina	05/06/92	14/07/92	DIZZINESS	14/06/92	Detail	14	16/06/92	14	1	2	4	1	3	3	3	1				
						Summary	16/06/92	14	1	2	4	1	3	3	3	1	YES					
						18/06/92	DYSURIA	Detail	7	18/06/92	7	1	2	4	1	3	3	3	1	YES		
								Summary	18/06/92	7	1	2	4	1	3	3	3	1	YES			
						26/06/92	HEADACHE	Detail	26	30/06/92	26	2	2	6	1	3	3	3	1	YES		
								Summary	30/06/92	26	2	2	6	1	3	3	3	1	YES			
						07/06/92	INSOMNIA	Detail	7	14/12/06/92	7	2	1	4	1	3	3	3	3	3	3	
								Summary	12/06/92	14	2	1	4	1	3	3	3	1	YES			
						25/06/92	MICTURITION DISORDER	Detail	21	16/07/92(*)	21	1	2	4	1	3	3	3	3	3	3	Y
								Summary	16/07/92(*)	21	1	2	4	1	3	3	3	3	3	3	Y	
						06/06/92	MOUTH DRY	Detail	7	16/07/92(*)	7	1	2	3	1	3	3	3	3	3	3	Y
								Summary	16/07/92(*)	7	1	2	3	1	3	3	3	3	3	3	Y	
10/06/92	PERINEAL PAIN MALE	Detail	7	14/07/92	7	1	2	4	1	3	3	3	3	3	3	3						
		Summary	14/07/92	42	1	2	4	1	3	3	3	3	3	3	1	YES						
11/06/92	TREMOR	Detail	7	11/06/92	7	1	2	3	1	3	3	3	3	3	3	3						
		Summary	20/06/92	21	1	2	3	1	3	3	3	3	3	3	1	YES						
16/06/92	VISION ABNORMAL	Detail	14	16/06/92	14	1	2	3	1	3	3	3	3	3	3	1	YES					
		Summary	16/06/92	14	1	2	3	1	3	3	3	3	3	3	1	YES						
02/07/92		Detail	35	16/07/92(*)	35	1	2	3	1	3	3	3	3	3	3	3	Y					
		Summary	16/07/92(*)	35	1	2	3	1	3	3	3	3	3	3	3	Y						

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=nona
 symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (c*) adverse event still present; end date = visit date
 (c) onset date missing: first report visit date used
 (c) onset date missing: start treatment date of report visit

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

67

9550082

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit	End date	Last report		Dis Hosp	Re app.	Out	Still present (C)		
											save	visit						
12	374	Placebo	09/06/92	05/07/92	SWEATING INCREASED	18/06/92	Detail	7	10/06/92	Summary	2	2	4	1	3	3	1	
											7	2	2	4	1	3	3	3
375	Imprazine	17/06/92	18/06/92	HEADACHE	18/06/92	Detail	0	18/06/92(*)	Summary	0	2						NO	
											0	2						
					SUICIDE ATTEMPT	18/06/92	Detail	7	18/06/92	Summary	2	2	3	3	1	2	3	1
											7	2	2	3	3	1	2	3
					VISION ABNORMAL	18/06/92	Detail	7	20/06/92	Summary	2	2	4	3	1	2	3	1
											7	2	2	4	3	1	2	3
13	Placebo	13/06/91	24/05/91	HEADACHE	17/06/91	Detail	7	14	25/06/91	Summary	2	2	4	1	3	3	3	
											2	2	4	1	3	3	3	1
14	Placebo	02/07/91	13/06/91	CONCENTRATION IMPAIRED	01/07/91(D)	Detail	0	13/06/91(*)	Summary	0	2						NO	
											0	2						
					DIZZINESS	05/07/91	Detail	7	05/07/91	Summary	1	1	2	3	1	2	3	3
											2	2	3	1	2	3	3	3
						09/07/91	Detail	16	09/07/91	Summary	2	2	3	3	1	2	3	3
											2	2	3	3	1	2	3	3
					SOMNOLENCE	01/07/91(D)	Detail	0	13/06/91(*)	Summary	2						NO	
											0	2						

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=drug withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Respp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=unusual, 5=unknown, 6=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) onset date missing: first report visit date used
(D) onset date missing: start treatment date of report visit

1606

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19

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PHARMACIA CHS RHD

REMOMETINE - PROTOCOL 20124/215
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Type record	Visit End No data	Last		Rel	Stud	Symp	Dis	RA	Out	Still			
			Start date	End date					visit	city										
13	14	Placebo	02/07/91	15/06/91	SWEATING INCREASED	Detail	42		2	3	2	1	3	3	3	3	Y			
						Summary		13/08/91(*)	42	2	3	2	1	3	3	3	3	Y		
			15	Intracranial	05/07/91	15/06/91	AGITATION	Detail	28		2	3	3	1	3	3	3	3	3	Y
								Detail	42		2	3	2	1	3	3	3	3	Y	
								Summary		15/08/91(*)	42	2	3	2	1	3	3	3	3	Y
								Detail	7		1	3	3	1	YES	3	3	3	3	Y
			Summary		15/08/91(*)	7	1	3	3	1	YES	3	3	3	3	Y				
			15	01/07/91	15/06/91	INFECTION FUNGAL	Detail	14							YES				Y	
							Summary		15/08/91(*)	14						YES				NO
			15	07/07/91	15/06/91	MOUTH DRY	Detail	7		2	1	2	1	3	3	3	3	3	3	Y
Detail	16						2	1	3	1	3	3	3	3	3	3	Y			
Detail	35						2	1	2	1	3	3	3	3	3	3	Y			
Detail	42						2	3	2	1	3	3	3	3	3	3	Y			
Summary		15/08/91(*)	42	2	1	2	1	3	3	3	3	3	3	Y						
15	05/07/91	15/06/91	NAUSEA	Detail	7		1	2	3	1	2	3	3	3	3	3	Y			
				Summary		15/08/91(*)	7	1	2	3	1	2	3	3	3	3	Y			
15	06/07/91	15/06/91	RHINITIS	Detail	7		2	2	4	1	YES	2	3	3	3	3	Y			
				Summary		15/08/91(*)	7	2	2	4	1	YES	2	3	3	3	Y			
15	11/07/91	15/06/91	SWEATING INCREASED	Detail	35		2	1	2	1	3	3	3	3	3	3	Y			
				Detail	42		2	3	3	1	3	3	3	3	3	3	Y			
				Summary		15/08/91(*)	42	2	1	2	1	3	3	3	3	3	Y			
				Detail	21		2	1	2	1	3	3	3	3	3	3	Y			
Summary		15/08/91(*)	21	2	1	2	1	3	3	3	3	3	3	Y						

Severity: 0=Unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=drug withdrawn, 4=drug discontinued
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=same
 Systematic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (P) adverse event still present and date = visit date
 (D) onset date missing: first report visit date used
 (E) onset date missing: start treatment date of report visit

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71

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PHARMACIA CNS RAD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.3

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit record	End No date	Last report	Save Hist	Rel Ship	Stud Sym	Disapp	Reapp	Out	Skill	Present (C)														
																				visit	ship	drug	trac	Hisp	app.	come	present	(C)					
13	15	Imipramine	03/12/91 - 16/01/92	AGITATION																YES													
																					Detail	7	2	1	4	4	2	1	3	3			
																					Detail	21	30/12/91	1	1	3	1	2	3	3	1		
																					Summary	30/12/91	21	2	1	3	4	2	3	3	1		
																					Detail	7	3	2	3	4	2	1	3	3			
																					Detail	21	30/12/91	1	2	3	1	2	3	3	1		
																					Summary	30/12/91	21	3	2	3	4	2	3	3	1		
																					Detail	28	2	1	3	1	2	3	3	3			
																					Detail	42	2	1	2	3	2	1	3	3	Y		
																					Summary	20/01/92(*)	42	2	1	2	3	2	1	3	3	Y	
																					Detail	7	2	2	4	4	2	1	3	3			
																					Detail	21	05/12/91	1	2	2	1	2	3	3	1		
Summary	05/12/91	21	2	2	2	4	2	3	3	1																							
Detail	42	5	2	3	3	2	1	3	3	Y																							
Summary	20/01/92(*)	42	5	2	3	3	2	1	3	3	Y																						
17	Reboxetine	21/05/92 - 01/07/92	AGITATION																		YES												
																						Detail	26	2	3	3	1	2	3	3	3	5	
																						Detail	42	2	1	2	3	2	1	3	3	Y	
																						Summary	20/01/92(*)	42	2	1	2	3	2	1	3	3	Y
																						Detail	21	2	1	3	1	2	3	3	3		
																						Detail	28	17/06/92	2	1	3	1	2	3	3	1	
																						Summary	17/06/92	28	2	1	3	1	2	3	3	1	
																						Detail	42	2	1	3	1	2	3	3	3	Y	
																						Summary	02/07/92(*)	42	2	1	3	1	2	3	3	3	Y
																						Detail	7	1	1	3	1	2	3	3	3		
																						Detail	21	2	1	3	1	2	3	3	3	1	
																						Summary	17/06/92	28	2	1	3	1	2	3	3	1	
Detail	7	2	1	3	1	2	3	3	3	1																							
Summary	22/05/92	28	2	1	3	1	2	3	3	1																							
Detail	7	2	1	3	1	2	3	3	3	Y																							

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4= doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (*) adverse event used for statistical analysis
 (C) adverse event still present; end date = visit date
 (2) onset date missing; first report visit date used
 (3) onset date missing; start treatment date of report visit

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72

9550082

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 201247015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit No	End date	Last report visit	Saves rcty	Hist	Rel	Stud	Symp	Dis	Re	Out	Still
13	17	Reboxetine	21/05/92	01/07/92	MOUTH DRY	22/05/92	Summary	02/07/92(+)	7	2	1	3	1	2	3	3	3	3	3	Y
		Reboxetine	24/06/92	02/06/92	AGITATION	13/07/92	Detail 28	03/08/92	1	1	3	1	2	3	3	3	3	3	3	3
							Detail 42	03/08/92	1	1	3	1	2	3	3	3	3	3	3	1
							Summary	03/08/92	42	1	1	3	1	2	3	3	3	3	3	1
							Detail 42	27/02/92	1	1	3	1	2	3	3	3	3	3	3	Y
							Summary	03/08/92(+)	42	1	1	3	1	2	3	3	3	3	3	Y
							Detail 35	24/07/92	35				YES							
							Summary	26/07/92	35				YES							
							Detail 0	16/06/92	0				2							
							Detail 7	16/06/92	7				2	1	4	1	2	3	3	3
							Detail 14	06/07/92	14				2	1	4	1	2	3	3	1
							Summary	06/07/92	14	2	1	4	1	2	3	3	3	3	1	NO
409		Reboxetine	18/12/91	26/01/92	MICTURITION DISORDER	02/01/92	Detail 26	20/01/92(+)	26	1	2	3	1	2	3	3	3	3	3	Y
							Summary	20/01/92(+)	26	1	2	3	1	2	3	3	3	3	3	Y
							Detail 7	11/12/91	7				2	3	3	1	2	3	3	3
							Detail 14	20/12/91	14				2	2	3	1	2	3	3	1
							Summary	20/12/91	14	2	2	3	1	2	3	3	3	3	3	1
410		Placebo	14/02/92	26/03/92	AGITATION	21/02/92	Detail 14	19/03/92	14				2	1	2	1	2	3	3	3
							Detail 35	19/03/92	35				1	1	2	1	2	3	3	3
							Summary	19/03/92	35	2	1	2	1	2	3	3	3	3	3	1
							Detail 0	05/02/92(2)	0				2							
							Detail 7	26/03/92(+)	7	2	1	2	1	2	3	3	3	3	3	Y
							Summary	26/03/92(+)	7	2	1	2	1	2	3	3	3	3	3	Y

Severities: 0=unknown, 1=mild, 2=moderate, 3=severe.
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Respp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=None
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(Y) adverse event still present; end date = visit date
(2) onset date missing; first report visit date used
(3) onset date missing; start treatment date of report visit

Centre Patient Drug	Treatment Start date	End date	Adverse event	Onset date	Type Visit record	End date	Last report visit	Rel. Study	Hist. any drug	Dis. Hosp. app.	Re. Out. Still			
13 410 Placebo	16/02/92	26/05/92	RHINITIS	11/02/92	Detail	7		2	1	2	1	3		
					Detail	14	27/02/92	2	1	3	1	2	3	3
					Summary	14	27/02/92	2	1	2	1	2	3	1
						14	2	1	2	1	2	3	3	1
						14	2	1	2	1	2	3	3	1
411 Imipramine	20/03/92	08/05/92	ASTHENIA	13/03/92	Detail	35		2	1	3	1	2	3	
					Summary	28/03/92(*)	35	2	1	3	1	2	3	3
					Detail	21	11/05/92(*)	2	1	3	1	3	3	3
					Summary	11/05/92(*)	21	2	1	3	1	3	3	3
						21	2	1	3	1	3	3	3	3
	22/04/92		CONCENTRATION IMPAIRED		Detail	28		2	3	3	1	3	3	
					Detail	42		2	3	3	1	3	3	3
					Summary	11/05/92(*)	42	2	3	3	1	3	3	3
						42	2	3	3	1	3	3	3	3
						42	2	3	3	1	3	3	3	3
	04/06/92		CONSTIPATION		Detail	14		2	2	3	1	2	3	
					Summary	11/05/92(*)	14	2	2	3	1	2	3	3
						14	2	2	3	1	2	3	3	3
						14	2	2	3	1	2	3	3	3
						14	2	2	3	1	2	3	3	3
	13/06/92		FATIGUE		Detail	21		2	1	3	1	3	3	
					Summary	11/05/92(*)	21	2	1	3	1	3	3	3
						21	2	1	3	1	3	3	3	3
						21	2	1	3	1	3	3	3	3
						21	2	1	3	1	3	3	3	3
	10/06/92		HEADACHE		Detail	20		2	2	4	1	2	3	
					Summary	11/05/92(*)	20	2	2	4	1	2	3	3
						20	2	2	4	1	2	3	3	3
						20	2	2	4	1	2	3	3	3
						20	2	2	4	1	2	3	3	3
	07/03/92		MICTURITION DISORDER		Detail	7		1	2	3	1	3	3	
					Detail	26		2	2	3	1	3	3	3
					Summary	11/05/92(*)	26	2	2	3	1	3	3	3
						26	2	2	3	1	3	3	3	3
						26	2	2	3	1	3	3	3	3
	25/03/92(*)		MOUTH DRY		Detail	0		1						
					Detail	7		2	1	5	1	2	3	3
					Detail	14		2	1	5	1	2	3	3
					Summary	13/04/92(*)	14	2	1	5	1	2	3	3
						14	2	1	5	1	2	3	3	3

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (*) adverse event used for statistical analysis
 (†) adverse event still present: end date = visit date
 (‡) onset date missing: first report visit date used
 (‡) onset date missing: start treatment date or report visit

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74

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PHARMACIA CNS 3&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Simp	Rpt	Hosp	App.	Same	Present	(C)						
																	Start date	End date	Adverse event	Onset date	Type record	Visit No
13	411	Imipramine	20/03/92	08/05/92	DORSA PERIPHERAL	25/03/92(D)	Detail	0		0	1						NO					
							Summary	11/05/92(*)														
							Detail	0		2	1	4	1	3	3	3	1					
14	19	Reboxetine	10/04/92	06/05/92	SLEEP DISORDER	25/02/92(D)	Detail	7	06/06/92	2	1	4	1	3	3	3	1	NO				
							Summary	06/06/92		7	2	1	4	1	3	3	3	1				
							Detail	35	11/05/92(*)		2	1	4	1	3	3	3	3	3	3	3	Y
14	19	Reboxetine	10/04/92	06/05/92	SWEATING INCREASED	25/04/92	Detail	21	06/10/92	2	2	3	1	2	3	3	1	YES				
							Summary	06/10/92		21	2	2	3	1	2	3	3	3	1			
							Detail	26	07/05/92(*)		28	1	2	2	1	3	3	3	3	3	3	Y
20	19	Imipramine	29/04/92	09/06/92	URINARY TRACT INFECTION	04/04/92	Detail	7	15/06/92	2	2	6	1	YES	3	3	1	NO				
							Summary	15/06/92		7	2	3	6	1	YES	3	3	3	1			
							Detail	7	30/04/92		1	2	6	4	3	3	3	3	3	3	1	YES
20	19	Imipramine	29/04/92	09/06/92	MOUTH DRY	29/04/92	Detail	7	10/06/92(*)	7	2	2	1	3	3	3	3	Y				
							Summary	10/06/92(*)		7	2	2	1	3	3	3	3	3	3	3	3	Y
							Detail	7	10/06/92(*)		7	2	2	1	3	3	3	3	3	3	3	3

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=drug withdrawn, 4=stop.
 Hospital: 1=required, 2=not req., 3=not appl.
 Disposition: 1=0, 2=yes, 3=not appl.
 Symptomatic treatment: 0=no, 1=yes.
 (C) adverse event used for statistical analysis
 (D) adverse event still present: end date = visit date
 (E) onset date missing: first report visit date used
 (F) onset date missing: start treatment date of report visit

1611

PHARMACIA CNS RED

REBOMETINE - PROTOCOL 28124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Sx	Mist	Rpt	Ship	Drug	Trea	Hosp	Dis	Rt	Out	Still	Present (c)		
																							Present (c)	
14	20	Isipramine	29/04/92	09/06/92	SWEATING INCREASED	29/04/92	Detail	7	1	2	2	1	3	3	3	3	3	3	3	3	3	3	3	
							Detail	21	2	2	1	3	3	3	3	3	3							
							Detail	26	1	2	2	1	3	3	3	3	3							
							Detail	42	1	2	2	1	3	3	3	3	3							
							Summary	16/06/92	42	2	2	2	1	3	3	3	3	1	YES					
							Detail	42	1	2	2	1	2	3	3	3	3	3	Y					
							Summary	10/06/92(*)	42	1	2	2	1	2	3	3	3	3	Y					
							Detail	7	2	2	2	1	3	3	3	3	3	3	3					
							Detail	21	2	2	2	1	3	3	3	3	3	3	3					
							Summary	20/05/92	21	2	2	2	1	3	3	3	3	3	1	YES				
							Detail	7	1	2	2	1	3	3	3	3	3	3	3					
							Detail	42	1	2	2	1	3	3	3	3	3	3	1	YES				
							Summary	10/06/92	42	1	2	2	1	3	3	3	3	3	1	YES				
							21	Isipramine	20/07/92	26/08/92	ABDOMINAL PAIN	20/07/92	Detail	7	1	2	2	1	3	3	3	3	3	3
Detail	21	1	2	3	1	3							3	3	3	3								
Detail	35	1	2	2	1	3							3	3	3	3	3	Y						
Summary	24/08/92(*)	35	1	2	2	1							3	3	3	3	3	Y						
Detail	7	1	2	2	1	3							3	3	3	3	3	3						
Detail	21	1	2	2	1	3							3	3	3	3	3	1	YES					
Summary	18/08/92	21	1	2	2	1							3	3	3	3	3	1	YES					
Detail	7	1	2	2	1	3							3	3	3	3	3	3						
Detail	21	1	2	2	1	3							3	3	3	3	3	1	YES					
Summary	03/08/92	14	1	2	2	1							3	3	3	3	3	1	YES					
Detail	7	2	2	2	1	3							3	3	3	3	3	1	YES					
Detail	21	2	2	2	1	3							3	3	3	3	3	1	YES					
Summary	02/08/92	14	2	2	2	1							3	3	3	3	3	1	YES					
Detail	14	1	2	2	1	3							3	3	3	3	3	3	Y					
Summary	26/08/92(*)	14	1	2	2	1	3	3	3	3	3	3	Y											

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe. -- History: 1=present before, 2=not observe bef., 3=unknown
 Study drug: 1=no change, 2=dose reduced, 3=stop, 4=withdrawn, 5=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=none, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (a) onset date missing: first report visit date used
 (b) onset date missing: start treatment date of report visit

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76

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PHARMACIA DHS RED
 REBOXTINE - PROTOCOL 20126/015
 Listing No.: 17.0
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Lett report	Save city	Hist ary	Mist drug	Rel Hosp	Stud APP.	Sym APP.	Dis APP.	Rm APP.	Out APP.	Still APP.	
			Start date	End date																
14	21	Imipramine	20/07/92	24/08/92	23/07/92	Detail	14	01/08/92	14	1	2	2	1	3	3	3	3	1	YES	
						Summary		01/08/92		14	1	2	2	1	3	3	3	1		
15	25	Reboxetine	10/06/91	29/07/91	03/07/91	Detail	35	22/07/91	35	2	2	3	1	2	3	3	3	1	YES	
						Summary		22/07/91		35	2	2	3	1	2	3	3	1		
						Detail	14	01/07/91		2	1	4	1	3	3	3	3	1	YES	
						Summary		01/07/91		14	2	1	4	1	3	3	3	1		
						Detail	21	06/07/91		2	3	4	1	2	3	3	3	1	YES	
						Summary		06/07/91		21	2	3	4	1	2	3	3	1		
						Detail	7	19/06/91		1	2	5	1	2	3	3	3	1	YES	
						Summary		19/06/91		14	1	2	5	1	2	3	3	1		
						Detail	7	22/06/91		2	1	3	1	YES	2	3	3	1	YES	
						Summary		22/06/91		7	2	1	3	1	YES	2	3	3	1	
						Detail	35	22/07/91		35	2	1	6	1	YES	3	3	1	YES	
						Summary		22/07/91		35	2	1	6	1	YES	3	3	1		
						Detail	7	23/06/91		7	2	2	3	1	YES	2	3	3	1	YES
						Summary		23/06/91		7	2	2	3	1	YES	2	3	3	1	
						Detail	14	27/06/91		2	2	2	1	2	3	3	3	3	3	Y
						Summary		27/06/91		14	2	2	2	1	2	3	3	3	3	Y
						Detail	21	03/07/91		2	2	2	1	2	3	3	3	3	3	Y
						Summary		03/07/91		21	2	2	2	1	2	3	3	3	3	Y
						Detail	35	22/07/91		35	2	2	2	1	3	3	3	3	3	Y
						Summary		22/07/91		42	2	2	2	1	2	3	3	3	3	Y
						Detail	21	03/07/91		2	2	3	1	2	3	3	3	3	3	Y
						Summary		03/07/91		21	2	3	1	2	3	3	3	3	3	Y
						Detail	25	22/07/91		1	2	3	1	2	3	3	3	3	3	Y
						Summary		22/07/91		35	2	2	3	1	2	3	3	3	3	Y

Severity: Blanket: 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=suspected, 5=unknown, 6=None
 Symptomatic treatment: 0=no, 1=yes
 (C) Adverse event used for statistical analysis
 (Y) Adverse event still present; end date = visit
 (M) Onset date missing; first report visit date used
 (S) Onset date missing; start treatment date of report visit

1613

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PHARMACIA CNS RED

REBOMTINE - PROTOCOL 2012/015
Listing No.: 17-0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit record	End date	Last report	Save	Hist	Re	Out	SKILL											
										visit	freq	any	ship	drug	tree	Mosp	appr.	some	present	(C)						
15	25	Rebomtine	16/06/91	28/07/91	SOMNOLENCE	06/07/91		Detail	21			2	2	3	1	2	3	3	3							
								Detail	28			2	2	3	1	2	3	3	3							
								Detail	35			2	2	3	1	2	3	3	3	3						
								Summary	42			2	2	3	1	2	3	3	3	3						
								Summary	30/07/91(*)	62	2	2	3	1	2	3	3	3	3	Y	YES					
26	Placebo		20/06/91	01/08/91	PRIMARY TRACT INFECTION	06/07/91		Detail	21			1	2	6	1	3	3	3	3							
								Detail	28			1	2	6	1	3	3	3	1							
								Detail	35			1	2	6	1	3	3	3	1							
								Summary	42			26	1	2	6	1	3	3	3	1						
								Summary	13/07/91	26	1	2	6	1	3	3	3	1			YES					
			27/06/91		ABDOMINAL PAIN			Detail	14			2	2	4	1	2	3	3	3							
								Detail	21			2	2	4	1	2	3	3	1							
								Detail	28			2	2	4	1	2	3	3	1							
								Summary	42			21	2	2	4	1	2	3	3	1						
								Summary	06/07/91	21	2	2	4	1	2	3	3	1			YES					
			18/07/91		DIZZINESS			Detail	28			1	2	3	1	2	3	3	3							
								Detail	35			1	2	4	1	3	3	3	1							
								Detail	42			1	2	3	1	2	3	3	1							
								Summary	42			35	1	2	3	1	2	3	3	1						
								Summary	20/07/91	35	1	2	3	1	2	3	3	1			YES					
			14/06/91(*)		HEADACHE			Detail	0			2														
								Summary	01/08/91(*)	0	2															
			25/06/91		MOUTH DRY			Detail	7			1	2	3	1	3	3	3	3							
								Detail	14			1	2	2	1	2	3	3	3							
								Detail	21			1	2	2	1	2	3	3	1							
								Summary	42			21	1	2	2	1	2	3	3	1						
								Summary	09/07/91	21	1	2	2	1	2	3	3	1			YES					
			15/07/91					Detail	28			2	2	2	1	2	3	3	3							
								Detail	35			2	2	2	1	2	3	3	3							
								Detail	42			2	2	2	1	2	3	3	3	3						
								Summary	42			42	2	2	2	1	2	3	3	3	3					
								Summary	01/08/91(*)	42	2	2	2	1	2	3	3	3	Y	YES						
			05/07/91		RHINITIS			Detail	21			1	2	6	1	2	3	3	3							
								Detail	28			1	2	6	1	2	3	3	3							
								Detail	35			1	2	6	1	2	3	3	3	1						
								Summary	20/07/91	1	2	6	1	2	3	3	3	1								

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
Study drug: 1=none changed, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=default, 2=possible, 3=probable, 4=definite, 5=unknown, 6=none
Symptomatic treatment: 1=no, 2=yes
(*) adverse event used for statistical analysis
(C) onset date missing: first report visit date used
(S) onset date missing: start treatment date of report visit

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74

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PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20124/015
Listings No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	Save visit city	Mitt drug	Rel ship	Stud Symp	Dis app.	Re app.	Out app.	Skill	Present (c)	
																			01/28/91
15	26	Placebo	20/04/91	01/28/91	RHINITIS	06/07/91	Summary	20	07/91	35	1	2	4	1	2	3	3	1	YES
					SOMNOLENCE	21/07/91	Detail	55		1	2	3	1		3	3	3	3	
							Detail	62		1	2	3	1		3	3	3	3	Y
							Summary	01/08/91(*)		42	1	2	3	1	3	3	3	3	Y
					TONGUE ULCERATION	09/07/91	Detail	21		2	2	6	1		2	3	3	3	
							Detail	20	16/07/91	2	2	6	1		2	3	3	1	YES
							Summary	16/07/91		26	2	2	6	1	2	3	3	1	
					VISION ABNORMAL	27/04/91	Detail	14		1	2	2	1		2	3	3	3	
							Detail	21		1	2	2	1		3	3	3	3	
							Detail	20		1	2	2	1		3	3	3	3	
							Detail	35		2	2	2	1		3	3	3	5	
							Detail	62		2	2	2	1		3	3	3	5	Y
							Summary	01/08/91(*)		62	2	2	2	1	2	3	3	5	Y
27	Imipramine	02/07/91	13/08/91		APPETITE INCREASED	06/07/91	Detail	7		1	2	5	1		2	3	3	3	
							Detail	14		2	2	5	1		2	3	3	3	
							Detail	21		2	2	5	1		3	3	3	3	
							Detail	26		2	2	5	1		3	3	3	3	
							Detail	35		2	2	5	1		3	3	3	3	
							Detail	62		2	2	5	1		3	3	3	3	Y
							Summary	13/08/91(*)		42	2	2	5	1	2	3	3	3	Y
					CONFUSION	03/07/91	Detail	7	05/07/91	2	1	4	1		2	3	3	1	YES
							Summary	05/07/91		7	2	1	4	1	2	3	3	1	
					DIZZINESS	05/07/91	Detail	7		2	2	3	1		2	3	3	3	
							Detail	14		2	2	3	1		2	3	3	3	
							Detail	21		2	2	3	1		3	3	3	3	
							Detail	26		1	2	3	1		3	3	3	3	
							Detail	35	06/08/91	1	2	3	1		3	3	3	3	
							Detail	62	06/08/91	1	2	3	1		3	3	3	3	1
							Summary	06/08/91		35	2	2	3	1	2	3	3	3	1

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=na change, 2=dose reduced, 3=drug withdrawn, 4=stop- inter.
 Hospital: 1=readmit, 2=not req., 3=not app. -- Outcome: 1=recovered, 2=rel. with seq., 3=still present, 4=death
 Disapp./Rapp.: 1=no, 2=yes, 3=not app. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (d) adverse event still present: end date = visit date
 (e) onset date missing: first report visit date used
 (f) onset date missing: start treatment date of report visit

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73

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PHARMACIA CNS M20
 REROKETINE - PROTOCOL 2012K/015
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	Last report visit	RLM only	Stud drug	Stopp	Disapp.	Re	Dis	Still				
15	27	Imipramine	02/07/91	15/08/91		MOUTH DRY	06/07/91	Detail	7		1	2	2	1	2	3	3	3			
					Detail	14		1	2	2	1	2	3	3	3						
					Detail	21		1	2	2	1	2	3	3	3						
					Detail	26		1	2	2	1	2	3	3	3						
					Detail	35		1	2	2	1	2	3	3	3						
					Detail	42		2	2	2	1	2	3	3	3						
					Summary	13/08/91(*)		42	2	2	2	1	2	3	3	3	Y				
					Detail	14		2	2	3	1	2	3	3	3						
					Detail	21		2	2	3	1	2	3	3	3						
					Summary	28/07/91		26	2	3	1	2	3	3	3	1	YES				
28	Reboxetine	08/08/91	19/09/91			NAUSEA	12/07/91	Detail	14		2	2	3	1	2	3	3	3			
					Detail	21		2	2	3	1	2	3	3	3						
					Summary	28/07/91		26	2	3	1	2	3	3	3	1	YES				
					Detail	42		1	2	3	1	2	3	3	3	1	YES				
					Summary	12/08/91		42	1	2	3	1	2	3	3	1	YES				
					Detail	7		7	05/07/91	Detail	7		05/07/91	3	1	6	1	2	3	3	1
					Summary	05/07/91		7	3	1	6	1	2	3	3	1	YES				
					Detail	14		14	15/07/91	Detail	14		15/07/91	2	1	6	1	2	3	3	1
					Summary	15/07/91		14	2	1	6	1	2	3	3	1	YES				
					Summary	05/07/91		7	3	1	6	1	2	3	3	1	YES				
28	Reboxetine	08/08/91	19/09/91			SWEATING INCREASED	02/07/91	Detail	7		05/07/91	3	1	6	1	2	3	3	1		
					Summary	05/07/91		7	3	1	6	1	2	3	3	1	YES				
					Detail	14		14	15/07/91	Detail	14		15/07/91	2	1	6	1	2	3	3	1
					Summary	15/07/91		14	2	1	6	1	2	3	3	1	YES				
					Detail	28		28	08/08/91	Detail	28		08/08/91	2	2	2	1	YES			
					Detail	35		2	2	2	1	YES									
					Detail	42		2	2	2	1	YES									
					Detail	42		2	2	2	1	YES									
					Summary	29/09/91(*)		42	2	2	2	1	YES								
					Summary	07/09/91		35	2	2	3	1	3	3	3	1	YES				
28	Reboxetine	08/08/91	19/09/91			HEADACHE	08/08/91	Detail	7		13/08/91	1	2	3	1	3	3	3	1		
					Summary	10/08/91		7	1	2	3	1	3	3	3	1	YES				
					Detail	21		2	2	5	1	3	3	3	3						

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=unknown, 5=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (D) adverse event still present end date = visit date
 (E) onset date missing: first report visit date used
 (F) onset date missing: start treatment date of report visit

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PHARMACIA CNS R&D

REMONELINE - PROTOCOL 20126/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit	End record	No date	Last report visit	Save visit	Rel. to study	Drug	Time	Disapp.	Recovery	Still present	Outcomes	Still present					
15	28	Rebouxline	05/06/91	15/09/91	15/09/91	HOT FLUSHES	15/06/91	Detail	28	31/06/91		28	1	2	5	1	3	3	3	1	3	3	1	YES		
								Summary		31/06/91		28	2	2	5	1	3	3	3	1	3	3	1	YES		
								Detail	14			2	1	4	1	YES	3	3	3	3	3	3	3	3	3	
								Detail	21			2	1	4	1	YES	3	3	3	3	3	3	3	3	3	
								Detail	26			2	1	4	1	YES	3	3	3	3	3	3	3	3	3	
								Detail	35			2	1	4	1	YES	3	3	3	3	3	3	3	3	3	
								Detail	42	13/09/91		2	1	4	1	YES	3	3	3	3	3	3	3	3	3	
								Summary		13/09/91		42	2	1	4	1	YES	3	3	3	3	3	3	3	1	YES
								Detail	7	05/06/91		2	2	2	1		3	3	3	3	1	3	3	3	1	YES
								Summary		05/06/91		7	2	2	2	1	3	3	3	3	1	3	3	3	1	YES
								Detail	7			2	1	4	1		3	3	3	3	3	3	3	3	3	
								Detail	14			1	1	4	1		3	3	3	3	3	3	3	3	3	
								Detail	21	26/06/91		1	1	4	1		3	3	3	3	3	3	3	3	3	
								Summary		26/06/91		21	2	1	4	1	3	3	3	3	1	3	3	3	1	YES
								Detail	20	10/06/91		2	2	2	5	1	3	3	3	3	1	3	3	3	1	YES
								Summary		10/06/91		20	2	2	5	1	3	3	3	3	1	3	3	3	1	YES
								Detail	21			2	2	6	1		3	3	3	3	3	3	3	3	3	
								Detail	26			2	2	6	1	YES	3	3	3	3	3	3	3	3	3	
								Summary		07/09/91		35	2	2	6	1	YES	3	3	3	3	3	3	3	1	YES
29	Placebs		29/06/91	19/09/91	19/09/91	DIZZINESS	17/09/91	Detail	21			21	1	2	5	1	3	3	3	3	3	3	3	3	3	Y
								Summary		19/09/91		21	1	2	5	1	3	3	3	3	3	3	3	3	3	Y
								Detail	0			2	1	6	1		3	3	3	3	3	3	3	3	3	
								Detail	7			2	1	6	1		3	3	3	3	3	3	3	3	3	
								Detail	14	06/09/91		2	1	6	1		3	3	3	3	3	3	3	3	3	
								Summary		06/09/91		14	2	1	6	1	3	3	3	3	3	3	3	3	3	NO
								Detail	14	09/09/91		2	1	6	1		3	3	3	3	3	3	3	3	3	1

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
Study drug: 1=no change, 2=dose reduced, 3=drug withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=suspectible, 4=unknown, 5=none
Symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present; end date = visit date
(2) onset date missing; first report visit date used
(3) onset date missing; start treatment date of report visit

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PHARMACIA CIS H&D
 REMOXYLINE - PROTOCOL 20124/715
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report	Svlt rity	Rel Ship	Stud Drug	Svmp Hosp	Dis app.	Rs app.	Out app.	Skill Present	IC
15	29	Pilscebo	29/08/91	14/10/91	HEADACHE	08/09/91	Summary	09/09/91	Summary	14	2	1	6	1	3	3	3	1	YES
36	Imipramine	09/09/91	15/10/91	MOUTH DRY	05/09/91	05/09/91	Detail	7	Detail	7	2	2	1	1	3	3	3	3	YES
							Detail	14	Detail	14	2	2	1	1	3	3	3	3	YES
							Detail	21	Detail	21	2	2	1	1	3	3	3	3	YES
							Detail	26	Detail	26	2	2	1	1	3	3	3	3	YES
							Detail	35	Detail	35	2	2	1	1	3	3	3	3	YES
							Detail	42	Detail	42	2	2	1	1	3	3	3	3	YES
							Summary	15/10/91(*)	Summary	42	2	2	1	1	3	3	3	3	YES
							Detail	7	Detail	7	2	2	1	1	3	3	3	3	YES
							Detail	14	Detail	14	2	2	1	1	3	3	3	3	YES
							Detail	21	Detail	21	2	2	1	1	3	3	3	3	YES
							Detail	26	Detail	26	2	2	1	1	3	3	3	3	YES
							Detail	35	Detail	35	2	2	1	1	3	3	3	3	YES
							Detail	42	Detail	42	1	2	1	1	3	3	3	3	YES
							Summary	15/10/91(*)	Summary	62	2	2	1	1	3	3	3	3	YES
							Detail	26	Detail	26	3	2	1	1	3	3	3	3	YES
							Summary	30/09/91	Summary	26	3	2	1	1	3	3	3	3	YES
							Detail	42	Detail	42	3	2	1	1	3	3	3	3	YES
							Summary	14/10/91	Summary	42	3	2	1	1	3	3	3	3	YES
							Detail	7	Detail	7	1	2	1	1	3	3	3	3	YES
							Detail	14	Detail	14	1	2	1	1	3	3	3	3	YES
							Summary	10/09/91	Summary	14	1	2	1	1	3	3	3	3	YES
403	Imipramine	04/10/91	14/11/91	CONSTIPATION	14/10/91	14/10/91	Detail	14	Detail	14	2	1	1	1	3	3	3	3	YES
							Detail	21	Detail	21	2	2	1	1	3	3	3	3	YES
							Detail	26	Detail	26	2	2	1	1	3	3	3	3	YES
							Detail	35	Detail	35	2	2	1	1	3	3	3	3	YES
							Detail	42	Detail	42	2	2	1	1	3	3	3	3	YES
							Summary	05/11/91	Summary	35	2	1	1	1	3	3	3	3	YES
							Detail	21	Detail	21	2	2	1	1	3	3	3	3	YES
							Detail	28	Detail	28	2	3	1	1	3	3	3	3	YES

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Severity: 0=unknown, 1=mild, 2=moderate, 3=severe,
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. --- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Respa.: 1=yes, 2=yes, 3=not appl. --- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (*) adverse event used for statistical analysis
 (†) adverse event still present; end date = visit date
 (‡) onset date missing; first report visit date used
 (‡) onset date missing; start treatment date of report visit

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit	End	Last	Rpt	Sav	Hist	Rel	Stud	Symp	Dis	Ra	Out	Skill						
			Start date	End date																					
35	403	Imipramine	14/11/91	14/11/91	DIZZINESS		Summary	26/10/91	26	2	2	3	1	3	3	3	3	1	YES						
							Detail	02/11/91	35	02/11/91	2	2	5	1	3	3	3	1							
							Summary	02/11/91	35	2	2	5	1	3	3	3	3	1						YES	
							Detail	09/11/91	42	11/11/91	2	2	3	1	3	3	3	1							
							Summary	11/11/91	42	2	2	3	1	3	3	3	3	1						YES	
							Detail	29/10/91	21																
							Summary	30/10/91	26	30/10/91	1	1	5	1	3	3	3	3	1						YES
							Detail	04/10/91	7																
							Summary	04/10/91	14	2	2	1	1	3	3	3	3	3	1						
							Detail	10/10/91	21																
							Summary	12/10/91	28	12/10/91	2	2	1	3	3	3	3	3	1						
							Detail	01/10/91	7																
Summary	01/10/91	14	26/10/91	1	1	3	1	3	3	3	3	1													
Detail	16/10/91	14																							
Summary	16/10/91	21	26/10/91	2	1	4	1	3	3	3	3	1													
Detail	31/10/91	28																							
Summary	05/11/91(*)	28	05/11/91(*)	2	2	1	4	1	3	3	3	1													
Detail	16/10/91	14																							
Summary	16/10/91	14	21/10/91	2	2	4	1	3	3	3	3	1													

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl.
Disab./Retire.: 1=no, 2=yes, 3=not appl.
Symptomatic treatment: 1=no, 1=yes
(*) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(*) onset date missing: first report visit date used
(*) onset date missing: start treatment date of report visit

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83

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 2012/4/915
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

S	C	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report	Save	Hist	Rel	Stud	Symp	Dis	Re	Out	Still	Present (C)
15	406	Reboxetine	08/10/91	05/11/91	NERVOUSNESS	16/10/91	Summary	21/10/91	Summary	14	2	2	4	1	3	3	3	3	3	1	YES	
			17/10/91	SWEATING INCREASED	17/10/91	Detail	14		Detail	2	1	4	1	3	3	3	3	3	3	3		
						Detail	21		Detail	2	1	4	1	1	3	3	3	3	3	3		
						Detail	20	03/11/91	Detail	2	1	4	1	3	3	3	3	3	3	3	1	YES
						Summary	03/11/91		Summary	20	2	1	4	1	1	3	3	3	3	1		
			01/12/91	07/01/92	MOUTH DRY	01/12/91	Detail	7	Detail	2	2	2	1	3	3	3	3	3	3	3		
						Detail	14		Detail	2	2	2	1	3	3	3	3	3	3	3		
						Detail	21	15/12/91	Detail	1	2	2	1	3	3	3	3	3	3	1	YES	
						Summary	15/12/91		Summary	21	2	2	2	1	3	3	3	3	3	1		
			04/12/91	14/01/92	HEADACHE	04/12/91	Detail	7	Detail	2	1	4	1	3	3	3	3	3	3	3		
						Detail	14	12/12/91	Detail	2	1	4	1	3	3	3	3	3	3	1	YES	
						Summary	12/12/91		Summary	14	2	1	4	1	3	3	3	3	3	1		
			13/12/91			13/12/91	Detail	14	Detail	2	1	4	1	3	3	3	3	3	3	3		
						Detail	21	23/12/91	Detail	2	1	4	1	YES	3	3	3	3	3	1	YES	
						Summary	23/12/91		Summary	21	2	1	4	1	YES	3	3	3	3	1		
			25/12/91			25/12/91	Detail	26	Detail	2	1	4	1	3	3	3	3	3	3	3		
						Detail	35	01/01/92	Detail	2	1	4	1	3	3	3	3	3	3	1	YES	
						Summary	01/01/92		Summary	35	2	1	4	1	3	3	3	3	3	3	Y	
						Detail	42	14/01/92(=)	Detail	42	2	1	4	1	YES	3	3	3	3	3	Y	
						Summary	14/01/92(=)		Summary	42	2	1	4	1	YES	3	3	3	3	3	Y	
			26/12/91		NAUSEA	26/12/91	Detail	26	Detail	1	2	3	1	3	3	3	3	3	3	3		
						Detail	35		Detail	1	2	3	1	3	3	3	3	3	3	3		
						Detail	42	12/01/92	Detail	42	1	2	3	1	1	3	3	3	3	1	YES	
						Summary	12/01/92		Summary	42	1	2	3	1	1	3	3	3	3	1		
			03/02/92	04/03/92	HEADACHE	03/02/92	Detail	14	Detail	2	2	4	1	YES	3	3	3	3	3	3		
						Detail	21	04/02/92	Detail	2	2	4	1	YES	3	3	3	3	3	1	YES	
						Summary	04/02/92		Summary	21	2	2	4	1	YES	3	3	3	3	1		
			19/02/92			19/02/92	Detail	35	Detail	2	1	4	1	3	3	3	3	3	3	1	YES	
						Detail	35	23/02/92	Detail	2	1	4	1	3	3	3	3	3	3	1	YES	
						Summary	23/02/92		Summary	35	2	1	4	1	3	3	3	3	3	1		

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe. -- History: 1=present before, 2=not observed before, 3=unknown
 Study drug: 1=no change, 2=dose reduced, 3=not withdrawn, 4=stop, 5=inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reasp.: 1=seq, 2=seq, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=unsubstantiated, 5=none
 Symptomatic treatment: 0=none, 1=yes
 (C) adverse event used for statistical analysis
 (P) adverse event still present; end date = visit date
 (M) onset date missing; first report visit date used
 (S) onset date missing; start treatment date of report visit

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64

PHARMACIA CNS RED

REMOETINE - PROTOCOL 20124/015
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient ID	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit No	Last report date	Sae	Hist	Rel	Stud	Swep	Dis	Re	Out	Still	Disse	Comm	Present	(c)	
																								visit rity
15	406	Placebo	20/01/92	04/03/92	INGENHIA	11/02/92	35	Detail	35	35	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
					NAUSEA	02/02/92	21	Detail	21	21	4	1	3	5	3	1								
							16/02/92	35	Summary	35	21	2	4	1	3	3	1							YES
							27/02/92	42	Detail	42	42	1	2	3	1	3	3	1						YES
							02/02/92	14	Summary	14	2	2	4	1	3	3	3	1						
							02/02/92	21	Detail	21	2	2	4	1	3	3	3	1						YES
							28/02/92	35	Summary	35	21	2	2	4	1	3	3	3	1					YES
618		Placebo	30/01/92	12/02/92	CONSTIPATION	28/02/92	42	Detail	42	42	2	2	2	1	YES	3	3	3	3	3	3	3	3	Y
							21/02/92	26	Summary	26	42	2	2	2	1	YES	3	3	3	3	3	3	3	Y
							21/02/92	42	Detail	42	1	1	5	1	3	3	3	3	3	3	3	3	3	Y
							18/02/92	42	Summary	42	1	1	4	1	3	3	3	3	3	3	3	3	3	Y
							18/02/92	42	Detail	42	1	1	4	1	3	3	3	3	3	3	3	3	3	Y
							18/02/92	14	Summary	14	1	2	3	1	3	3	3	3	3	3	3	3	3	Y
							31/01/92	7	Detail	7	1	2	2	1	3	3	3	3	3	3	3	3	3	Y
							08/02/92	42	Summary	42	14	1	2	2	1	3	3	3	3	3	3	3	3	Y
							12/02/92	42	Detail	42	1	2	2	1	3	3	3	3	3	3	3	3	3	Y
							12/02/92	42	Summary	42	1	2	2	1	3	3	3	3	3	3	3	3	3	Y

Severely: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
 Study drug: 1= no change, 2= dose reduced, 3= def. withdrawn, 4= temp. inter.
 Hospital: 1= required, 2= not req., 3= not appl.
 Disapp./Reapp.: 1= no, 2= yes, 3= not appl.
 Symptomatic treatment: 0= no, 1= yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present; end date = visit date
 (**) onset date missing; first report visit date used
 (8) onset date missing; start treatment date of report visit

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05

9550082

PHARMACIA CNS X&D
 RERODIETINE - PROTOCOL 20124/015
 Listing No.: 17.0
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Start date	End date	Treatment	Onset date	Type	Visit	No	Data	Last report	Save	Hist	R1	Stud	Symp	Dis	Re	Out	Still	Present (C)	
																						Adverse event
15	419	Placebo	26/04/92	03/06/92	AMBIETY	26/04/92	Detail	7	01/05/92		7	1	2	3	1	2	3	3	3	1	YES	
							Summary		01/05/92		7	1	2	3	1	2	3	3	3	1	YES	
					APPETITE INCREASED	29/04/92	Detail	7			2	2	3	1	2	3	3	3	3			
							Detail	14	05/05/92		2	2	2	1	3	3	3	3	1			
							Summary		05/05/92		14	2	2	2	1	2	3	3	3	1	YES	
					BACK PAIN	22/05/92	Detail	20			2	1	6	1	YES	2	3	3	3			
							Detail	42			2	1	6	1	YES	2	3	3	3	3	Y	
							Summary		05/06/92(*)		42	2	1	6	1	YES	2	3	3	3	Y	
					HEADACHE	11/05/92	Detail	16			2	2	4	1	YES	2	3	3	3			
							Detail	21	25/05/92		2	2	4	1	YES	2	3	3	3	1		
							Summary		25/05/92		21	2	2	4	1	YES	2	3	3	3	1	YES
					NAUSEA	06/05/92	Detail	7	06/05/92		2	2	2	1	2	3	3	3	1			
							Summary		06/05/92		7	2	2	1	2	3	3	3	1	YES		
							Detail	14			1	2	2	1	2	3	3	3				
							Detail	21	21/05/92		1	2	2	1	2	3	3	3	1			
							Summary		21/05/92		21	1	2	2	1	2	3	3	3	1	YES	
					TREMOR	31/05/92	Detail	35	01/06/92		2	2	4	1	2	3	3	3	1			
							Summary		01/06/92		35	2	2	4	1	2	3	3	3	1	YES	
					URINARY TRACT INFECTION	05/06/92	Detail	42			2	2	6	1	YES	3	3	3	3	Y		
							Summary		05/06/92(*)		42	2	2	6	1	YES	3	3	3	3	Y	
					VOMITING	06/05/92	Detail	7	06/05/92		2	2	2	1	2	3	3	3	1			
							Summary		06/05/92		7	2	2	2	1	2	3	3	3	1	YES	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. later.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=resolved, 2=rec. with seq., 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (c) adverse event used for statistical analysis
 (*) adverse event still present: end date = visit date
 (C) onset date missing: first report visit date used
 (B) onset date missing: start treatment date of report visit

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 1 Patient: 1 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/04/91		01/05/91		22/05/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/91	14.60		14.50		14.40	
HT	37-47 (X)	01/03/91	42.00		43.00		41.00	
RBC	3.8-5.8 (10 ¹² /L)	01/03/91	4.78		4.82		4.72	
HBC	4-11 (10 ⁹ /L)	01/03/91	8.40		8.50		10.30	
HBC: N	2-7.5 (10 ⁹ /L)	01/03/91	6.70		5.90		7.80	>
HBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	1.30		1.90		1.80	
HBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.10		0.20		0.10	
HBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.30		0.40		0.50	
HBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.00		0.10		0.00	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	372.00		349.00		341.00	
NA+	137-145 (MMOL/L)	01/03/91	144.00		140.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.80		3.90		3.90	
CL-	100-111 (MMOL/L)	01/03/91	106.00		105.00		105.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/91	2.35		2.27		2.24	
PO4--	0.7-1.4 (MMOL/L)	01/03/91	0.91		0.91		1.04	
SGOT	5-40 (U/L)	01/03/91	32.00		30.00		15.00	
SGPT	5-55 (U/L)	01/03/91	9.00		14.00		28.00	
GAMMA GT	10-80 (U/L)	01/03/91	27.00		20.00		33.00	
LDH	300-550 (U/L)	01/03/91	520.00		455.00		450.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	63.00		68.00		73.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91			5.30		5.40	
UREA	2.5-7.5 (MMOL/L)	01/03/91	3.00		4.40		7.70	>
CREATININE	60-110 (UMOL/L)	01/03/91	76.00		97.00		88.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	259.00		208.00		251.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	12.00		8.00		7.00	
TOT. PROTEINS	62-81 (G/L)	01/03/91	77.00		78.00		77.00	
ALBUMINE	35-50 (G/L)	01/03/91	42.00		45.00		42.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	4.84		4.29		5.17	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	0.66		0.80		0.66	
TSH	0.2-3.2 (MU/L)	01/03/91	1.30					
T4	11-24 (PMOL/L)	01/03/91	21.70					

1623

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 2 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/04/91		06/05/91		27/05/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/91	13.30	<	13.70	<	13.80	<
HT	41-53 (X)	01/03/91	39.00	<	40.00	<	40.00	<
RBC	4.5-6.5 (10 ¹² /L)	01/03/91	4.01	<	4.12	<	4.23	<
WBC	4-11 (10 ⁹ /L)	01/03/91	5.30		5.50		5.60	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	3.30		2.80		3.14	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	1.60		2.29		1.85	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.00		0.19		0.17	
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.20		0.39		0.45	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.10		0.10			
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	358.00		278.00		282.00	
NA+	137-145 (MMOL/L)	01/03/91	140.00		140.00		138.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.80		4.60		4.70	
CL-	98-110 (MMOL/L)	01/03/91	104.00		108.00		102.00	
Ca++	2.1-2.55 (MMOL/L)	01/03/91	2.38		2.33		2.35	
PO4--	0.75-1.4 (MMOL/L)	01/03/91	1.06		1.00		1.15	
SGOT	5-40 (U/L)	01/03/91	58.00	>	34.00		19.00	
SGPT	5-55 (U/L)	01/03/91	86.00	>	56.00	>	27.00	
GAMMA GT	10-80 (U/L)	01/03/91	115.00	>	47.00		31.00	
LDH	300-550 (U/L)	01/03/91	705.00	>	687.00	>	693.00	>
ALK. PHOSPH.	19-95 (U/L)	01/03/91	84.00		55.00		55.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	5.10		5.60		6.70	>
UREA	2.5-7.5 (MMOL/L)	01/03/91	3.20		5.00		4.20	
CREATININE	60-110 (UMOL/L)	01/03/91	103.00		109.00		106.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	433.00		437.00		377.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	21.00		8.00		8.00	
TOT. PROTEINS	60-80 (G/L)	01/03/91	81.00	>	78.00		77.00	
ALBUMINE	38-50 (G/L)	01/03/91	44.00		42.00		42.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	7.67	>>	7.52	>>	7.24	>>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	2.47	>>	1.46		2.34	>>
TSH	0.2-3.2 (MU/L)	01/03/91	0.90					
T4	11-24 (PMOL/L)	01/03/91	13.50					

1624

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 1 Patient: 3 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/05/91		27/05/91		17/06/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/91	14.50		14.90		15.40	
HT	41-53 (%)	01/03/91	42.00		43.00		45.00	
RBC	4.5-6.5 (10 ¹² /L)	01/03/91	4.63		4.73		4.96	
WBC	4-11 (10 ⁹ /L)	01/03/91	7.80		8.20		7.70	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	3.40		3.30		2.70	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	3.30		2.70		2.77	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.50		1.60	>>	1.31 >>	
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.50		0.60		0.85 >	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.10		0.00		0.08	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	283.00		261.00		267.00	
NA+	137-145 (MMOL/L)	01/03/91	140.00		141.00		142.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.80		4.20		3.90	
CL-	98-110 (MMOL/L)	01/03/91	108.00		102.00		105.00	
Ca++	2.1-2.55 (MMOL/L)	01/03/91	2.30		2.32		2.31	
PO4--	0.75-1.4 (MMOL/L)	01/03/91	1.16		1.24		1.31	
SGOT	5-40 (U/L)	01/03/91	17.00		21.00		18.00	
SGPT	5-55 (U/L)	01/03/91	4.00	<	13.00		10.00	
GAMMA GT	10-80 (U/L)	01/03/91	29.00		27.00		31.00	
LDH	300-550 (U/L)	01/03/91	440.00		776.00	>	517.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	88.00		110.00	>	82.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	5.30		4.50		4.80	
UREA	2.5-7.5 (MMOL/L)	01/03/91	6.60		6.40		5.70	
CREATININE	60-110 (UMOL/L)	01/03/91	90.00		87.00		94.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	419.00		355.00		368.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/91	5.00		7.00		10.00	
TOT. PROTEINS	60-80 (G/L)	01/03/91	71.00		76.00		75.00	
ALBUMINE	38-50 (G/L)	01/03/91	39.00		42.00		45.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	4.67		4.52		5.18	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	2.74	>>	2.57	>>	1.92 >	
TSH	0.2-3.2 (MU/L)	01/03/91	1.60					
T4	11-24 (PMOL/L)	01/03/91	14.60					

1625

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 4 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/06/91		25/06/91		16/07/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	03/06/91	15.10		13.80 <	14.00		
HT	41-53 (%)	03/06/91	44.00		41.00	41.00		
RBC	4.5-6.5 (10~12/L)	03/06/91	5.13		4.74	4.80		
HBC	4-11 (10~9/L)	03/06/91	11.00		9.00	7.90		
HBC: N	2-7.5 (10~9/L)	03/06/91	7.40		6.60	4.19		
HBC: L	1.3-3.6 (10~9/L)	03/06/91	2.80		1.70	2.92		
HBC: E	0-0.7 (10~9/L)	03/06/91	0.30		0.30	0.40		
HBC: H	0.2-0.8 (10~9/L)	03/06/91	0.40		0.20	0.32		
HBC: B	0-0.2 (10~9/L)	03/06/91	0.10		0.10	0.08		
PLATELETS	150-400 (10~9/L)	03/06/91	277.00		166.00	199.00		
NA+	137-145 (MMOL/L)	03/06/91	141.00		141.00	140.00		
K+	3.5-5 (MMOL/L)	03/06/91	4.20		4.60	4.50		
CL-	98-110 (MMOL/L)	24/06/91			106.00	105.00		
Ca++	2.1-2.55 (MMOL/L)	24/06/91			2.28	2.30		
PO4--	3.5-5 (MG/DL)	03/06/91	4.20					
	0.75-1.4 (MMOL/L)	24/06/91			1.22	1.16		
SGOT	5-40 (U/L)	03/06/91	21.00		29.00	34.00		
SGPT	5-55 (U/L)	03/06/91	7.00		19.00	21.00		
GAMMA GT	10-80 (U/L)	03/06/91	26.00		22.00	21.00		
LDH	300-550 (U/L)	24/06/91			584.00 >	767.00 >		
ALK. PHOSPH.	19-95 (U/L)	03/06/91	70.00		51.00	49.00		
GLUCOSE	3.6-5.8 (MMOL/L)	03/06/91	5.70		4.90	4.80		
UREA	2.5-7.5 (MMOL/L)	24/06/91			5.20	5.90		
CREATININE	60-110 (UMOL/L)	03/06/91	115.00 >		95.00	94.00		
URIC ACID	180-440 (UMOL/L)	24/06/91			444.00 >	389.00		
TOT BILIRUBIN	3-22 (UMOL/L)	03/06/91	8.00		9.00	10.00		
TOT. PROTEINS	60-80 (G/L)	03/06/91	77.00		71.00	77.00		
ALBUMINE	38-50 (G/L)	03/06/91	39.00		41.00	45.00		
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	24/06/91			5.46	5.90 >		
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	24/06/91			1.49	0.93		
TSH	0.2-3.2 (MU/L)	03/06/91	1.90					
T4	11-24 (PMOL/L)	03/06/91	17.70					

1626

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 1 Patient: 5 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			12/06/91	02/07/91
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/03/91	16.00	14.40
HT	37-47 (2)	01/03/91	46.00	43.00
RBC	3.8-5.8 (10 ¹² /L)	01/03/91	5.20	4.71
MBC	4-11 (10 ⁹ /L)	01/03/91	8.80	7.30
MBC: N	2-7.5 (10 ⁹ /L)	01/03/91	3.87	3.40
MBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	4.31 >	3.30
MBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.09	0.10
MBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.53	0.40
MBC: B	0-0.2 (10 ⁹ /L)	01/03/91		0.20
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	403.00 >	372.00
NA+	137-145 (MMOL/L)	01/03/91	142.00	138.00
K+	3.5-5 (MMOL/L)	01/03/91	4.30	5.20 >
CL-	100-111 (MMOL/L)	01/03/91	107.00	106.00
Ca++	2.1-2.5 (MMOL/L)	01/03/91	2.37	2.38
PO4--	0.7-1.4 (MMOL/L)	01/03/91	1.09	1.10
SGOT	5-40 (U/L)	01/03/91	19.00	23.00
SGPT	5-55 (U/L)	01/03/91	12.00	3.00 <
GAMMA GT	10-80 (U/L)	01/03/91	29.00	25.00
LDH	300-550 (U/L)	01/03/91	493.00	403.00
ALK. PHOSPH.	19-95 (U/L)	01/03/91	79.00	69.00
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	5.80	4.40
UREA	2.5-7.5 (MMOL/L)	01/03/91	1.70 <	2.90
CREATININE	60-110 (UMOL/L)	01/03/91	67.00	75.00
URIC ACID	180-440 (UMOL/L)	01/03/91	330.00	308.00
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	9.00	9.00
TOT. PROTEINS	62-81 (G/L)	01/03/91	81.00	71.00
ALBUMINE	35-50 (G/L)	01/03/91	49.00	41.00
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	6.34 >	6.31 >
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	2.84 >>	1.93 >
TSH	0.2-3.2 (MU/L)	01/03/91	0.90	
T4	11-24 (PMOL/L)	01/03/91	20.70	

1627

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 6 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/05/91		13/06/91		08/07/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HR	12-16 (G/DL)	01/03/91	13.10		14.60		14.60	
HT	37-47 (X)	01/03/91	38.00		42.00		42.00	
RBC	3.8-5.8 (10 ¹² /L)	01/03/91	4.15		4.63		4.67	
WBC	4-11 (10 ⁹ /L)	01/03/91	7.60		8.90		6.10	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	4.40		5.40		3.10	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	2.60		2.90		2.30	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.10		0.10		0.20	
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.40		0.40		0.40	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.10		0.10		0.20	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	291.00		279.00		272.00	
NA+	137-145 (MMOL/L)	01/03/91	140.00		138.00		137.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.00		2.90 <<		4.80	
CL-	100-111 (MMOL/L)	01/03/91	102.00		95.00 <		100.00	
Ca ⁺⁺	2.1-2.5 (MMOL/L)	01/03/91	2.34		2.34		2.48	
PO ₄ ⁻⁻	0.7-1.4 (MMOL/L)	01/03/91	1.30		1.09		1.24	
SGOT	5-40 (U/L)	01/03/91	10.00		24.00		20.00	
SGPT	5-55 (U/L)	01/03/91	11.00		3.00 <		3.00 <	
GAMMA GT	10-80 (U/L)	01/03/91	15.00		18.00		17.00	
LDH	300-550 (U/L)	01/03/91	363.00		528.00		668.00 >	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	61.00		60.00		57.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	5.30		6.30 >		5.10	
UREA	2.5-7.5 (MMOL/L)	01/03/91	3.40		2.70		2.80	
CREATININE	60-110 (UMOL/L)	01/03/91	81.00		79.00		83.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	169.00 <		214.00		178.00 <	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	16.00		25.00 >		34.00 >	
TOT. PROTEINS	62-81 (G/L)	01/03/91	70.00		81.00		80.00	
ALBUMINE	35-50 (G/L)	01/03/91	41.00		46.00		47.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	4.80		5.58 >		5.37	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	0.90		0.99		1.17	
TSH	0.2-3.2 (MU/L)	01/03/91	1.00					
T4	11-24 (PMOL/L)	01/03/91	15.90					

1628

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 7 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/08/91		17/09/91		08/10/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/91	13.80		13.30		12.90	
HT	37-47 (%)	01/03/91	40.00		38.00		38.00	
RBC	3.8-5.8 (10 ¹² /L)	01/03/91	4.59		4.38		4.20	
HBC	4-11 (10 ⁹ /L)	01/03/91	7.60		5.60		6.00	
HBC: M	2-7.5 (10 ⁹ /L)	01/03/91	4.90		3.80		3.40	
HBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	2.20		1.50		2.00	
HBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.10		0.10		0.20	
HBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.30		0.30		0.20	
HBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.00		0.10		0.20	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	315.00		302.00		289.00	
NA+	137-145 (MMOL/L)	01/03/91	143.00		141.00		138.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.80		4.00		5.30 >	
CL-	100-111 (MMOL/L)	01/03/91	102.00		105.00		105.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/91	2.37		2.28		2.28	
PO4--	0.7-1.4 (MMOL/L)	01/03/91	1.10		1.09		1.04	
SGOT	5-40 (U/L)	01/03/91	29.00		23.00		27.00	
SGPT	5-55 (U/L)	01/03/91	18.00		6.00		20.00	
GAMMA GT	10-80 (U/L)	01/03/91	21.00		22.00		24.00	
LDH	300-550 (U/L)	01/03/91	432.00		336.00		381.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	61.00		51.00		53.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	4.90		3.30 <		4.40	
UREA	2.5-7.5 (MMOL/L)	01/03/91	2.50		2.50		1.50 <	
CREATININE	60-110 (UMOL/L)	01/03/91	76.00		70.00		79.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	275.00		224.00		234.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	15.00		13.00		12.00	
TOT. PROTEINS	62-81 (G/L)	01/03/91	82.00 >		77.00		75.00	
ALBUMINE	35-50 (G/L)	01/03/91	45.00		42.00		40.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	3.82		3.13 <		3.52	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	0.95		0.75		0.89	
TSH	0.2-3.2 (MU/L)	01/03/91	0.60					
T4	11-24 (PMOL/L)	01/03/91	19.90					

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1629

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 8 Treatment: Placobo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/09/91		28/09/91		19/10/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/91	15.30		14.60		15.20	
HT	41-53 (%)	01/03/91	45.00		43.00		45.00	
RBC	4.5-6.5 (10 ¹² /L)	01/03/91	4.92		4.71		4.89	
WBC	4-11 (10 ⁹ /L)	01/03/91	8.60		5.70		7.40	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	5.10		3.10		4.96	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	2.80		2.00		1.78	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.20		0.10		0.07	
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.40		0.20		0.59	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.20		0.20			
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	292.00		324.00		253.00	
NA+	137-145 (MMOL/L)	01/03/91	141.00		141.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.20		4.40		4.30	
CL-	98-110 (MMOL/L)	01/03/91	107.00		108.00		104.00	
Ca++	2.1-2.55 (MMOL/L)	01/03/91	2.42		2.31		2.42	
PO4--	0.75-1.4 (MMOL/L)	01/03/91	1.36		1.09		1.20	
SGOT	5-40 (U/L)	01/03/91	38.00		11.00		17.00	
SGPT	5-55 (U/L)	01/03/91	38.00		26.00		21.00	
GAMMA GT	10-80 (U/L)	01/03/91	30.00		26.00		24.00	
LDH	300-550 (U/L)	01/03/91	431.00		365.00		483.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	66.00		66.00		67.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	5.00		7.80 >>		6.20 >	
UREA	2.5-7.5 (MMOL/L)	01/03/91	6.40		5.50		5.30	
CREATININE	60-110 (UMOL/L)	01/03/91	85.00		55.00 <		62.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	275.00		229.00		242.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	6.00		6.00		9.00	
TOT. PROTEINS	60-80 (G/L)	01/03/91	74.00		71.00		74.00	
ALBUMINE	38-50 (G/L)	01/03/91	44.00		40.00		44.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	4.98		4.14		5.50	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	1.78 >		0.47		1.23	
TSH	0.2-3.2 (MU/L)	01/03/91	0.70				0.80	
T4	11-24 (PMOL/L)	01/03/91	12.30				11.60	

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 9 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/11/91		18/12/91		06/01/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/91	11.40	<	11.90	<	11.40	<
HT	37-47 (%)	01/03/91	33.00	<	35.00	<	33.00	<
RBC	3.8-5.8 (10 ¹² /L)	01/03/91	3.52	<	3.69	<	3.63	<
WBC	4-11 (10 ⁹ /L)	01/03/91	3.00	<	4.20		5.90	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	1.38	<<	2.69		4.00	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	1.17	<	0.97	<	1.50	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.03				0.10	
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.39		0.42		0.30	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.03		0.04		0.00	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	263.00		271.00		217.00	
NA+	137-145 (MMOL/L)	01/03/91	140.00		138.00		138.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.20		4.10		3.90	
CL-	100-111 (MMOL/L)	01/03/91	104.00		102.00		106.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/91	2.20		2.16		2.12	
PO4--	0.7-1.4 (MMOL/L)	01/03/91	1.20		1.17		1.21	
SGOT	5-40 (U/L)	01/03/91	29.00		30.00		35.00	
SGPT	5-55 (U/L)	01/03/91	27.00		23.00		28.00	
GAMMA GT	10-80 (U/L)	01/03/91	32.00		27.00		22.00	
LDH	300-550 (U/L)	01/03/91	423.00		461.00		547.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	48.00		46.00		40.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	4.50		4.60			
UREA	2.5-7.5 (MMOL/L)	01/03/91	1.70	<	3.00		3.00	
CREATININE	60-110 (UMOL/L)	01/03/91	83.00		74.00		72.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	265.00		201.00		230.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	8.00		7.00		8.00	
TOT. PROTEINS	62-81 (G/L)	01/03/91	74.00		75.00		72.00	
ALBUMINE	35-50 (G/L)	01/03/91	42.00		42.00		39.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	3.80		4.46		3.48	<
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	0.63		1.53		0.95	
TSH	0.2-3.2 (MU/L)	01/03/91	0.50				1.00	
T4	11-24 (PMOL/L)	01/03/91	17.20				12.30	

1631

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 10 Treatment: Placebo Sex: Male

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			04/09/91		15/10/91		04/11/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/91	15.40		15.30		14.70	
HT	41-53 (%)	01/03/91	45.00		45.00		44.00	
RBC	4.5-6.5 (10~12/L)	01/03/91	4.90		4.82		4.68	
MBC	4-11 (10~9/L)	01/03/91	8.90		6.10		8.50	
MBC: N	2-7.5 (10~9/L)	01/03/91	6.40		3.90		6.29	
MBC: L	1.3-3.6 (10~9/L)	01/03/91	1.80		1.60		1.62	
MBC: E	0-0.7 (10~9/L)	01/03/91	0.20		0.20		0.26	
MBC: M	0.2-0.8 (10~9/L)	01/03/91	0.40		0.30		0.34	
MBC: B	0-0.2 (10~9/L)	01/03/91	0.00		0.00			
PLATELETS	150-400 (10~9/L)	01/03/91	246.00		219.00		243.00	
NA+	137-145 (MMOL/L)	01/03/91	143.00		141.00		141.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.20		4.30		4.20	
CL-	98-110 (MMOL/L)	01/03/91	104.00		104.00		104.00	
Ca++	2.1-2.55 (MMOL/L)	01/03/91	2.42		2.46		2.30	
PO4--	0.75-1.4 (MMOL/L)	01/03/91	1.16		0.85		1.06	
SGOT	5-40 (U/L)	01/03/91	34.00		20.00		38.00	
SGPT	5-55 (U/L)	01/03/91	36.00		16.00		23.00	
GAMMA GT	10-80 (U/L)	01/03/91	42.00		33.00		31.00	
LDH	300-550 (U/L)	01/03/91	606.00 >		575.00 >		671.00 >	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	51.00		46.00		56.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	5.10		5.50		5.80	
UREA	2.5-7.5 (MMOL/L)	01/03/91	3.60		3.90		3.90	
CREATININE	60-110 (UMOL/L)	01/03/91	98.00		101.00		111.00 >	
URIC ACID	180-440 (UMOL/L)	01/03/91	297.00		309.00		308.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/91	13.00		13.00		17.00	
TOT. PROTEINS	60-80 (G/L)	01/03/91	78.00		75.00		74.00	
ALBUMINE	38-50 (G/L)	01/03/91	46.00		45.00		44.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	5.53 >		4.96		4.69	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	1.15		0.59		0.69	
TSH	0.2-3.2 (MU/L)	01/03/91	0.70					
T4	11-24 (PMOL/L)	01/03/91	15.20					

1632

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 1 Patient: 11 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	
			10/10/91	
			value	(*)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/03/91	11.70	<
HT	37-47 (%)	01/03/91	34.00	<
RBC	3.8-5.8 (10 ¹² /L)	01/03/91	3.71	<
HBC	4-11 (10 ⁹ /L)	01/03/91	5.10	
HBC: N	2-7.5 (10 ⁹ /L)	01/03/91	3.20	
HBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	1.40	
HBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.10	
HBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.30	
HBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.00	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	317.00	
NA+	137-145 (MMOL/L)	01/03/91	142.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.10	
CL-	100-111 (MMOL/L)	01/03/91	104.00	
Ca ⁺⁺	2.1-2.5 (MMOL/L)	01/03/91	2.33	
PO ₄ ⁻⁻	0.7-1.4 (MMOL/L)	01/03/91	0.83	
SGOT	5-40 (U/L)	01/03/91	32.00	
SGPT	5-55 (U/L)	01/03/91	17.00	
GAMMA GT	10-80 (U/L)	01/03/91	21.00	
LDH	300-550 (U/L)	01/03/91	496.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	54.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	6.80	>
UREA	2.5-7.5 (MMOL/L)	01/03/91	9.20	>
CREATININE	60-110 (UMOL/L)	01/03/91	116.00	>
URIC ACID	180-440 (UMOL/L)	01/03/91	361.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	13.00	
TOT. PROTEINS	62-81 (G/L)	01/03/91	74.00	
ALBUMINE	35-50 (G/L)	01/03/91	45.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	4.69	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	0.82	
TSH	0.2-3.2 (MU/L)	01/03/91	0.70	
T4	11-24 (PMOL/L)	01/03/91	14.50	

1633

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 12 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/10/91		15/11/91		05/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/91	14.00		14.00		13.30	
HT	37-47 (X)	01/03/91	41.00		41.00		39.00	
RBC	3.8-5.8 (10 ⁹ /L)	01/03/91	4.72		4.77		4.47	
WBC	4-11 (10 ⁹ /L)	01/03/91	7.60		6.40		8.50	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	4.30		3.70		5.10	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	2.70		2.20		2.70	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.20		0.10		0.30	
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.40		0.40		0.40	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.10		0.00		0.10	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	277.00		275.00		244.00	
NA+	137-145 (MMOL/L)	01/03/91	141.00		139.00		141.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.00		4.10		4.30	
CL-	100-111 (MMOL/L)	01/03/91	104.00		104.00		106.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/91	2.47		2.41		2.35	
PO4--	0.7-1.4 (MMOL/L)	01/03/91	1.09		1.17		1.19	
SGOT	5-40 (U/L)	01/03/91	15.00		35.00		35.00	
SGPT	5-55 (U/L)	01/03/91	19.00		26.00		15.00	
GAMMA GT	10-80 (U/L)	01/03/91	18.00		18.00		14.00	
LDH	300-550 (U/L)	01/03/91	547.00		583.00 >		567.00 >	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	73.00		82.00		77.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	5.20		6.00 >		4.40	
UREA	2.5-7.5 (MMOL/L)	01/03/91	7.00		6.10		7.40	
CREATININE	60-140 (UMOL/L)	01/03/91	90.00		95.00		87.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	279.00		326.00		234.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	10.00		9.00		7.00	
TOT. PROTEINS	62-84 (G/L)	01/03/91	81.00		77.00		79.00	
ALBUMINE	35-50 (G/L)	01/03/91	47.00		44.00		46.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	6.64 >		5.38		5.43	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	1.83 >		2.02 >		1.64	
TSH	0.2-3.2 (MU/L)	01/03/91	0.60		0.60		0.70	
T4	11-24 (PMOL/L)	01/03/91	14.90		13.10		13.20	

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1634

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 412 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/11/91		05/12/91		23/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/91	16.40		15.70		16.40	
HT	41-53 (%)	01/03/91	48.00		46.00		47.00	
RBC	4.5-6.5 (10 ⁹ /L)	01/03/91	5.36		5.15		5.29	
WBC	4-11 (10 ⁹ /L)	01/03/91	14.20	>	18.20	>>	10.70	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	10.00	>>	14.10	>>	7.00	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	3.50		3.60		3.00	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.20		0.40		0.20	
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.30		0.20		0.30	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.10		0.00		0.10	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	236.00		223.00		221.00	
NA+	137-145 (MMOL/L)	01/03/91	140.00		141.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.20		4.40		4.40	
CL-	98-110 (MMOL/L)	01/03/91	104.00		105.00		105.00	
Ca++	2.1-2.55 (MMOL/L)	01/03/91	2.44		2.53		2.39	
PO4--	0.75-1.4 (MMOL/L)	01/03/91	1.09		0.74	<	0.67	
SGOT	5-40 (U/L)	01/03/91	58.00	>	42.00	>	53.00	
SGPT	5-55 (U/L)	01/03/91	101.00	>	49.00		40.00	
GAMMA GT	10-80 (U/L)	01/03/91	46.00		39.00		42.00	
LDH	300-550 (U/L)	01/03/91	678.00	>	928.00	>	783.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	75.00		63.00		69.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	4.60		5.00		4.30	
UREA	2.5-7.5 (MMOL/L)	01/03/91	4.50		7.60	>	4.60	
CREATININE	60-110 (UMOL/L)	01/03/91	102.00		108.00		105.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	307.00		393.00		283.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	9.00		10.00		11.00	
TOT. PROTEINS	60-80 (G/L)	01/03/91	76.00		76.00		74.00	
ALBUMINE	38-50 (G/L)	01/03/91	43.00		41.00		40.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	5.75	>	4.35		4.92	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	2.36	>>	1.76	>	2.53	
TSH	0.2-3.2 (MU/L)	01/03/91	1.40		1.80		1.40	
T4	11-24 (PMOL/L)	01/03/91	10.40	<	13.00		15.10	

1635

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 1 Patient: 413 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/12/91		30/12/91		20/01/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/91	15.00		14.70		14.50	
HT	41-53 (Z)	01/03/91	46.00		43.00		43.00	
RBC	4.5-6.5 (10 ¹² /L)	01/03/91	4.74		4.48 <		4.49 <	
WBC	4-11 (10 ⁹ /L)	01/03/91	4.70		4.40		5.30	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	2.30		2.20		2.60	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	1.80		1.60		2.00	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.10		0.10		0.20	
WBC: H	0.2-0.8 (10 ⁹ /L)	01/03/91	0.50		0.40		0.50	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	154.00		188.00		174.00	
NA+	137-145 (MMOL/L)	01/03/91	141.00		143.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.10		3.60		3.90	
CL-	98-110 (MMOL/L)	01/03/91	103.00		104.00		103.00	
Ca++	2.1-2.55 (MMOL/L)	01/03/91	2.27		2.20		2.38	
PO4--	0.75-1.4 (MMOL/L)	01/03/91	0.57 <<		0.56 <<		0.77	
SGOT	5-40 (U/L)	01/03/91	50.00 >		47.00 >		30.00	
SGPT	5-55 (U/L)	01/03/91	46.00		44.00		39.00	
GAMMA GT	10-80 (U/L)	01/03/91	26.00		27.00		29.00	
LDH	300-550 (U/L)	01/03/91	739.00 >		651.00 >		479.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	78.00		76.00		81.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	4.50		3.80		3.50 <	
UREA	2.5-7.5 (MMOL/L)	01/03/91	7.40		8.20 >		7.30	
CREATININE	60-110 (UMOL/L)	01/03/91	95.00		106.00		95.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	345.00		403.00		310.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/91	14.00		10.00		10.00	
TOT. PROTEINS	60-80 (G/L)	01/03/91	76.00		76.00		79.00	
ALBUMINE	38-50 (G/L)	01/03/91	41.00		41.00		43.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	5.70 >		6.49 >		6.29 >	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	0.54		1.24		1.00	
TSH	0.2-3.2 (MU/L)	01/03/91	1.90		1.50		1.60	
T4	11-24 (PMOL/L)	01/03/91	25.00 >		14.90		17.20	

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 414 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			19/01/92
			value (e)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/03/91	15.50
HT	37-47 (%)	01/03/91	45.00
RBC	3.8-5.8 (10 ¹² /L)	01/03/91	5.10
WBC	4-11 (10 ⁹ /L)	01/03/91	8.20
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	5.00
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	2.60
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.10
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.50
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.10
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	188.00
NA+	137-145 (MMOL/L)	01/03/91	139.00
K+	3.5-5 (MMOL/L)	01/03/91	3.90
CL-	100-111 (MMOL/L)	01/03/91	103.00
SGOT	5-40 (U/L)	01/03/91	33.00
SGPT	5-55 (U/L)	01/03/91	18.00
GAMMA GT	10-80 (U/L)	01/03/91	22.00
ALK. PHOSPH.	19-95 (U/L)	01/03/91	90.00
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	4.40
UREA	2.5-7.5 (MMOL/L)	01/03/91	5.00
CREATININE	60-110 (UMOL/L)	01/03/91	82.00
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/91	15.00
TOT. PROTEINS	62-81 (G/L)	01/03/91	79.00
ALBUMINE	35-50 (G/L)	01/03/91	43.00
TSH	0.2-3.2 (MU/L)	01/03/91	1.00
T4	11-24 (PMOL/L)	01/03/91	5.00 <<

1637

(e) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 415 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/01/92		06/02/92		27/02/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/91	15.50		15.50		15.80	
HT	41-53 (%)	01/03/91	45.00		45.00		46.00	
RBC	4.5-6.5 (10 ⁹ /L)	01/03/91	4.48	<	4.45	<	4.61	
HBC	4-11 (10 ⁹ /L)	01/03/91	8.20		7.80		7.70	
HBC: N	2-7.5 (10 ⁹ /L)	01/03/91	5.00		4.40		4.40	
HBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	2.70		2.30		2.50	
HBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.10		0.10		0.10	
HBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.30		0.40		0.60	
HBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.10		0.10		0.10	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	343.00		331.00		352.00	
NA+	137-145 (MMOL/L)	01/03/91	139.00		141.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.10		3.30	<	4.20	
CL-	98-110 (MMOL/L)	01/03/91	105.00		98.00		100.00	
Ca++	2.1-2.55 (MMOL/L)	01/03/91	2.34				2.23	
PO4--	0.75-1.4 (MMOL/L)	01/03/91	0.97				0.91	
SGOT	5-40 (U/L)	01/03/91	28.00		36.00		32.00	
SGPT	5-55 (U/L)	01/03/91	36.00		35.00		44.00	
GAMMA GT	10-80 (U/L)	01/03/91	58.00		59.00		54.00	
LDH	300-550 (U/L)	01/03/91	497.00				539.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	57.00		64.00		63.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	5.00		6.60	>	4.30	
UREA	2.5-7.5 (MMOL/L)	01/03/91	6.50		3.30		7.00	
CREATININE	60-140 (UMOL/L)	01/03/91	94.00		105.00		96.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	541.00	>			425.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	14.00		9.00		12.00	
TOT. PROTEINS	60-80 (G/L)	01/03/91	79.00		73.00		72.00	
ALBUMINE	38-50 (G/L)	01/03/91	46.00		45.00		45.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	5.07		5.63	>	5.11	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	0.58		1.34		2.05	>
TSH	0.2-3.2 (MU/L)	01/03/91	0.90		0.70		0.60	
T4	11-24 (PMOL/L)	01/03/91	15.80		17.00		14.90	

1638

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 1 Patient: 416 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			20/01/92
			value (⊕)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/03/91	8.40 <<
HT	37-47 (%)	01/03/91	27.00 <<
RBC	3.8-5.8 (10 ¹² /L)	01/03/91	4.29
WBC	4-11 (10 ⁹ /L)	01/03/91	8.30
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	4.90
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	2.80
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.70
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.60
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.20
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	319.00
NA+	137-145 (MMOL/L)	01/03/91	138.00
K+	3.5-5 (MMOL/L)	01/03/91	4.10
CL-	100-111 (MMOL/L)	01/03/91	105.00
Ca ⁺⁺	2.1-2.5 (MMOL/L)	01/03/91	2.30
PO ₄ ⁻⁻	0.7-1.4 (MMOL/L)	01/03/91	1.23
SGOT	5-40 (U/L)	01/03/91	30.00
SGPT	5-55 (U/L)	01/03/91	19.00
GAMMA GT	10-80 (U/L)	01/03/91	17.00
LDH	300-550 (U/L)	01/03/91	394.00
ALK. PHOSPH.	19-95 (U/L)	01/03/91	74.00
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	4.50
UREA	2.5-7.5 (MMOL/L)	01/03/91	4.70
CREATININE	60-110 (UMOL/L)	01/03/91	74.00
URIC ACID	180-440 (UMOL/L)	01/03/91	201.00
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/91	8.00
TOT. PROTEINS	62-81 (G/L)	01/03/91	74.00
ALBUMINE	35-50 (G/L)	01/03/91	40.00
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	5.12
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	0.63
TSH	0.2-3.2 (MU/L)	01/03/91	100.00 >>
T4	11-24 (PMOL/L)	01/03/91	7.30 <<

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1639

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 1 Patient: 421 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/02/92		19/03/92		09/04/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/91	14.40		14.60		14.10	
HT	41-53 (X)	01/03/91	42.00		43.00		41.00	
RBC	4.5-6.5 (10 ¹² /L)	01/03/91	4.42	<	4.50		4.32	
WBC	4-11 (10 ⁹ /L)	01/03/91	7.30		10.00		8.60	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/91	3.10		5.10		2.49	
WBC: L	1.3-3.6 (10 ⁹ /L)	01/03/91	3.60		4.10	>	5.25	
WBC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.10		0.10		0.09	
WBC: M	0.2-0.8 (10 ⁹ /L)	01/03/91	0.50		0.60		0.77	
WBC: B	0-0.2 (10 ⁹ /L)	01/03/91	0.00		0.10		0.00	
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	329.00		320.00		383.00	
NA+	137-145 (MMOL/L)	01/03/91	141.00		141.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.70		4.30		4.70	
CL-	98-110 (MMOL/L)	01/03/91	102.00		101.00		100.00	
Ca ⁺⁺	2.1-2.55 (MMOL/L)	01/03/91	2.34		2.30		2.38	
PO4 ⁻⁻	0.75-1.4 (MMOL/L)	01/03/91	1.33		1.44	>	1.42	
SGOT	5-40 (U/L)	01/03/91	27.00		26.00		36.00	
SGPT	5-55 (U/L)	01/03/91	33.00		27.00		27.00	
GAMMA GT	10-80 (U/L)	01/03/91	201.00	>>	159.00	>	162.00	
LDH	300-550 (U/L)	01/03/91	579.00	>	550.00	>	591.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/91	85.00		76.00		79.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/91	4.80		4.40		5.00	
UREA	2.5-7.5 (MMOL/L)	01/03/91						
CREATININE	60-110 (UMOL/L)	01/03/91	96.00		103.00		98.00	
URIC ACID	180-440 (UMOL/L)	01/03/91	437.00		402.00		436.00	
TOT. BILIRUBIN	3-22 (UMOL/L)	01/03/91	20.00		14.00		17.00	
TOT. PROTEINS	60-80 (G/L)	01/03/91	82.00	>	82.00	>	82.00	
ALBUMINE	38-50 (G/L)	01/03/91	46.00	>	45.00	>>	46.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/91	7.02	>	7.74	>>	7.87	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/91	2.25	>	2.39	>>	1.84	
TSM	0.2-3.2 (MU/L)	01/03/91	1.90		2.40		2.40	
T4	11-24 (PMOL/L)	01/03/91	17.40		15.60		12.40	

1640

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Laboratory test	Range value	Range date	04/08/92				26/08/92				17/09/92			
			value	(c)	value	(c)	value	(c)	value	(c)				
HS	14-18 (G/DL)	01/03/91	14.80											
HT	41-53 (Z)	01/03/91	43.00											
RBC	4.5-6.5 (10 ¹² /L)	01/03/91	4.74											
HBC	4-11 (10 ⁹ /L)	01/03/91	7.40											
HRC: N	2-7.5 (10 ⁹ /L)	01/03/91	4.00											
HRC: L	1-3-3.6 (10 ⁹ /L)	01/03/91	2.22											
HRC: E	0-0.7 (10 ⁹ /L)	01/03/91	0.52											
HRC: B	0-2-0.8 (10 ⁹ /L)	01/03/91	0.15											
PLATELETS	150-400 (10 ⁹ /L)	01/03/91	244.00											
NA+	137-145 (MMOL/L)	01/03/91	142.00											
K+	3.5-5 (MMOL/L)	01/03/91	4.40											
Cl-	96-110 (MMOL/L)	01/03/91	103.00											
Ca++	2-1-2.55 (MMOL/L)	01/03/91	2.34											
PRO--	0.75-1.4 (MMOL/L)	01/03/91	1.07											
SGPT	5-40 (U/L)	01/03/91	53.00											
SGPT	5-55 (U/L)	01/03/91	40.00											
GGT	10-80 (U/L)	01/03/91	41.00											
LDH	300-550 (U/L)	01/03/91	542.00											
LDH	19-95 (U/L)	01/03/91	69.00											
ALK. PHOSPH.	3.6-5.8 (MMOL/L)	01/03/91	8.60											
GLUCOSE	2.5-7.5 (MMOL/L)	01/03/91	103.00											
UREA	60-110 (MMOL/L)	01/03/91	507.00											
CREATININE	60-110 (MMOL/L)	01/03/91	11.00											
URIC ACID	180-440 (UMOL/L)	01/03/91	72.00											
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/91	11.00											
TOT BILIRUBIN	60-80 (G/L)	01/03/91	47.00											
TOT. PROTEINS	3.5-5.5 (MMOL/L)	01/03/91	7.12											
ALBUMINE	3.4-1.75 (MMOL/L)	01/03/91	1.01											
TOT. CHOLEST.	0.2-3.2 (MMOL/L)	01/03/91	0.70											
TRIGLYCERIDES	11-24 (PMOL/L)	01/03/91	14.00											

1641

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/1 Patient: 49 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/05/91		08/06/91		29/06/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-18 (G/100ML)	01/05/91	14.00		12.20		13.10	
HT	35-60 (X)	01/05/91	42.60		35.70		37.20	
RBC	4-6 (10 ⁶ /MM ³)	01/05/91	4.43		3.77 <		3.98 <	
HBC	4.5-10.5 (10 ³ /MM ³)	01/05/91			6.20		5.10	
HBC: N	40-70 (X)	01/05/91	59.00		4.60		45.00	
HBC: L	20-40 (X)	01/05/91	26.00		41.70 >		44.00 >	
HBC: E	1-4 (X)	01/05/91	1.00				2.00	
HBC: M	3-7 (X)	01/05/91	13.00	>>	6.20		8.00 >	
HBC: B	0-1 (X)	01/05/91	1.00				1.00	
PLATELETS	150-450 (10 ³ /MM ³)	01/05/91	303.00		271.00		299.00	
NA+	135-145 (MMOL/L)	01/05/91	141.00				140.00	
K+	3.5-5 (MMOL/L)	01/05/91	3.90				3.90	
CL-	101-110 (MMOL/L)	01/05/91	103.00				102.00	
Ca ⁺⁺	2.15-2.6 (MMOL/L)	01/05/91	2.46		2.45		2.51	
PO ₄ ⁻	0.81-1.45 (MMOL/L)	01/05/91	1.16		1.39		1.06	
SGOT	6-35 (U/L)	01/05/91	29.00				19.00	
SGPT	6-35 (U/L)	01/05/91	18.00				31.00	
GAMMA GT	8-33 (U/L)	01/05/91	14.00				24.00	
LDH	120-280 (U/L)	01/05/91	220.00		165.00		223.00	
ALK. PHOSPH.	30-90 (U/L)	01/05/91	54.00		50.00		59.00	
GLUCOSE	3.9-6.1 (MMOL/L)	01/05/91	4.80				4.60	
UREA	2.5-6.5 (MMOL/L)	01/05/91	5.40				4.00	
CREATININE	50-110 (UMOL/L)	01/05/91	88.00				81.00	
URIC ACID	180-450 (UMOL/L)	01/05/91	183.00		275.00		315.00	
TOT BILIRUBIN	3-17.1 (UMOL/L)	01/05/91	8.60		7.40		13.80	
DIR BILIRUBIN	0-5.1 (UMOL/L)	01/05/91					3.90	
TOT. PROTEINS	60-80 (G/L)	01/05/91	68.00		62.00		81.00 >	
ALBUMINE	35-50 (G/L)	01/05/91	50.80	>	63.60 >		50.40 >	
TOT. CHOLEST.	4-6.4 (MMOL/L)	01/05/91	5.97				7.54 >	
TRIGLYCERIDES	0.78-1.65 (MMOL/L)	01/05/91	0.92				1.24	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.00		3.40		1.50	
GLOBULINS ALPHA 2	5-11 (G/L)	01/05/91	6.70		9.40		6.10	
GLOBULINS BETA	6-13 (G/L)	01/05/91	9.30		12.00		8.80	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	9.20		11.60		10.20	
TSH	0.2-4.3 (UU/ML)	01/05/91	1.20					
T4	10-26 (PMOL/L)	01/05/91	12.20					

1642

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/1 Patient: 50 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/12/91		16/01/92		06/02/92	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	11-18 (G/100ML)	01/05/91	14.40		13.50		12.70	
HT	35-60 (X)	01/05/91	42.00		39.40		39.40	
RBC	4-6 (10 ⁶ /MM ³)	01/05/91	4.38		4.19		4.29	
MBC	4.5-10.5 (10 ³ /MM ³)	01/05/91						
MBC: N	40-70 (X)	01/05/91	7.90		6.50		6.90	
MBC: L	20-40 (X)	01/05/91	55.00		66.00		59.00	
MBC: E	1-4 (X)	01/05/91	39.00		19.00	<	35.00	
MBC: M	3-7 (X)	01/05/91	4.00		4.00		4.00	
MBC: B	0-1 (X)	01/05/91	2.00	<	9.00	>	4.00	
PLATELETS	150-450 (10 ³ /MM ³)	01/05/91	0.00		2.00	>>	0.00	
NA+	135-145 (MMOL/L)	01/05/91	286.00		264.00		339.00	
K+	3.5-5 (MMOL/L)	01/05/91	140.00		139.00		139.00	
CL-	101-110 (MMOL/L)	01/05/91	4.00		4.00		3.70	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	104.00		104.00		102.00	
PO4--	0.81-1.45 (MMOL/L)	01/05/91	2.29		2.21		2.30	
SGOT	6-35 (U/L)	01/05/91	1.01		0.87		0.88	
SGPT	6-35 (U/L)	01/05/91	56.00	>	16.00		16.00	
GAMMA GT	8-33 (U/L)	01/05/91	39.00	>	21.00		12.00	
LDH	120-280 (U/L)	01/05/91	52.00	>	22.00		15.00	
ALK. PHOSPH.	30-90 (U/L)	01/05/91	229.00		159.00		151.00	
GLUCOSE	3.9-6.1 (MMOL/L)	01/05/91	31.00		31.00		34.00	
UREA	2.5-6.5 (MMOL/L)	01/05/91	6.10		4.60		5.20	
CREATININE	50-140 (UMOL/L)	01/05/91	4.20		3.40		4.90	
URIC ACID	180-450 (UMOL/L)	01/05/91	79.00		76.00		92.00	
TOT. BILIRUBIN	3-17.1 (UMOL/L)	01/05/91	200.00		270.00		342.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	40.70		3.80		3.80	
ALBUMINE	35-50 (G/L)	01/05/91	75.00		69.00		72.00	
TOT. CHOLEST.	4-6.4 (MMOL/L)	01/05/91	42.00		45.70		45.30	
TRIGLYCERIDES	0.78-1.65 (MMOL/L)	01/05/91	6.89	>	5.07		4.94	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	1.92	>	0.60	<	0.88	
GLOBULINS ALPHA 2	5-11 (G/L)	01/05/91	2.50		1.90		3.40	
GLOBULINS BETA	6-13 (G/L)	01/05/91	8.40		6.00		6.70	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	9.40		6.90		8.30	
TSH	0.2-4.3 (UU/ML)	01/05/91	9.30		8.50		8.30	
T4	10-26 (PMOL/L)	01/05/91	24.80					

1643

(ϕ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/1 Patient: 51 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/01/92		24/02/92		16/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-18 (G/100ML)	01/05/91	14.30		13.10		13.40	
HT	35-60 (X)	01/05/91	41.90		38.50		39.40	
RBC	4-6 (10 ⁶ /MM ³)	01/05/91	4.58		4.23		4.32	
WBC	4.5-10.5 (10 ³ /MM ³)	01/05/91			6.10		6.90	
WBC: N	40-70 (X)	01/05/91	79.00	>	69.00		77.00 >	
WBC: L	20-40 (X)	01/05/91	17.00	<	24.00		18.00 <	
WBC: E	1-4 (X)	01/05/91	2.00		0.00	<	3.00 <	
WBC: M	3-7 (X)	01/05/91	2.00	<	7.00		2.00 <	
WBC: B	0-1 (X)	01/05/91	0.00		0.00		0.00	
PLATELETS	150-450 (10 ³ /MM ³)	01/05/91	283.00		227.00		245.00	
NA+	135-145 (MMOL/L)	01/05/91	141.00		142.00		142.00	
K+	3.5-5 (MMOL/L)	01/05/91	3.70		3.30	<	3.80	
CL-	101-110 (MMOL/L)	01/05/91	105.00		104.00		105.00	
Ca ⁺⁺	2.15-2.6 (MMOL/L)	01/05/91	2.17		2.19		2.20	
PO ₄ ⁻⁻	0.81-1.45 (MMOL/L)	01/05/91	1.17		1.12		1.05	
SGOT	6-35 (U/L)	01/05/91	10.00		18.00		10.00	
SGPT	6-35 (U/L)	01/05/91	8.00		12.00		16.00	
GAMMA GT	8-33 (U/L)	01/05/91	13.00		12.00		14.00	
LDH	120-280 (U/L)	01/05/91	162.00		145.00		186.00	
ALK. PHOSPH.	30-90 (U/L)	01/05/91	40.00		37.00		40.00	
GLUCOSE	3.9-6.1 (MMOL/L)	01/05/91	4.60		4.80		4.70	
UREA	2.5-6.5 (MMOL/L)	01/05/91	4.90		4.80		5.90	
CREATININE	50-110 (UMOL/L)	01/05/91	75.00		73.00		75.00	
URIC ACID	180-450 (UMOL/L)	01/05/91	220.00		229.00		206.00	
TOT. BILIRUBIN	3-17.1 (UMOL/L)	01/05/91	11.00		11.90		6.30	
TOT. PROTEINS	60-80 (G/L)	01/05/91	68.00		63.00		67.00	
ALBUMINE	35-50 (G/L)	01/05/91	41.40		41.90		44.70	
TOT. CHOLEST.	4-6.4 (MMOL/L)	01/05/91	5.72		3.94	<	5.48	
TRIGLYCERIDES	0.78-1.65 (MMOL/L)	01/05/91	1.16		0.91		0.86	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.00		1.80		1.80	
GLOBULINS ALPHA 2	5-11 (G/L)	01/05/91	6.70		5.60		6.10	
GLOBULINS BETA	6-13 (G/L)	01/05/91	7.60		5.60	<	5.80 <	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	10.30		8.10		8.60	
TSH	0.2-4.3 (UU/ML)	01/05/91	3.90					
T4	10-26 (PMOL/L)	01/05/91	18.00					

16/4

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/2 Patient: 43 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			11/04/91		13/05/91	
			value	(e)	value	(e)
Laboratory test	Range value	Range date				
HB	115-180 (G/L)	11/03/91	123.00		130.00	
HT	0.37-0.47 (L/L)	11/03/91	0.38		0.39	
RBC	4-5 (10 ⁶ /UL)	11/03/91	3.74	<	3.97 <	
WBC	4-10 (10 ³ /MM3)	11/03/91	5.48		6.10	
WBC: N	1.8-7.5 (10 ³ /MM3)	11/03/91	3.51		3.75	
WBC: L	1.5-4 (10 ³ /MM3)	11/03/91	1.47	<	1.54	
WBC: E	0.04-0.7 (10 ³ /MM3)	11/03/91	0.03	<	0.11	
WBC: M	0.2-1 (10 ³ /MM3)	11/03/91	0.38		0.46	
WBC: B	0-0.1 (10 ³ /MM3)	11/03/91	0.10		0.03	
PLATELETS	115-400 (10 ³ /UL)	11/03/91	165.00		171.00	
NA+	135-145 (MMOL/L)	11/03/91	137.00		137.00	
K+	3.8-4.8 (MMOL/L)	11/03/91	4.50		3.70 <	
CL-	98-108 (MMOL/L)	11/03/91	102.00		102.00	
Ca++	2.2-2.6 (MMOL/L)	11/03/91	2.16	<	2.12 <	
PO4--	0.8-1.4 (MMOL/L)	11/03/91			1.31	
SGOT	10-45 (U/L)	11/03/91	11.00		16.00	
SGPT	10-45 (U/L)	11/03/91	6.00	<	18.00	
GAMMA GT	5-45 (U/L)	11/03/91	18.00		21.00	
ALK. PHOSPH.	40-110 (U/L)	11/03/91	43.00		58.00	
GLUCOSE	4.5-5 (MMOL/L)	11/03/91	4.70		5.10 >	
UREA	3.5-7.5 (MM/L)	11/03/91	4.60		4.30	
CREATININE	45-90 (UMOL/L)	11/03/91	98.20	>	98.50 >	
URIC ACID	150-360 (UMOL/L)	11/03/91	176.00		268.00	
TOT BILIRUBIN	4-20 (UMOL/L)	11/03/91	15.00		6.00	
DIR BILIRUBIN	0-20 (UMOL/L)	11/03/91	12.00		5.00	
TOT. PROTEINS	60-75 (G/L)	11/03/91	78.00	>	79.00 >	
ALBUMINE	30.6-50.2 (G/L)	11/03/91	43.10		42.40	
TOT. CHOLEST.	4-6 (MMOL/L)	11/03/91	3.88	<	4.30	
TRIGLYCERIDES	0.5-1.5 (MMOL/L)	11/03/91	0.90		2.03 >>	
GLOBULINS ALPHA 1	1.8-3.7 (G/L)	11/03/91	1.40	<	1.80	
GLOBULINS ALPHA 2	4.2-9 (G/L)	11/03/91	5.10		9.10 >	
GLOBULINS BETA	6-12 (G/L)	11/03/91	6.80		8.40	
GLOBULINS GAMMA	6-13 (G/L)	11/03/91	11.30		14.10 >	
TSH	0.1-5 (MU/L)	11/03/91	1.63			
T4	10-23 (PMOL/L)	11/03/91	17.90			

1645

(e) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/2 Patient: 44 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/07/91		09/08/91		28/08/91	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	115-180 (G/L)	10/05/91	121.00		117.00		146.00	
HT	38-48 (X)	10/05/91	34.00 <		35.00 <		39.10	
RBC	4-5 (10 ⁶ /UL)	10/05/91	3.80 <		3.90 <		4.16	
HBC	4-10 (10 ³ /MM3)	10/05/91	6.95		5.30		5.29	
HBC: N	1.8-7.5 (10 ³ /MM3)	10/05/91	3.98		3.80		2.81	
HBC: L	1.5-4 (10 ³ /MM3)	10/05/91	2.23		1.90		1.97	
HBC: E	0.04-0.7 (10 ³ /MM3)	10/05/91	0.06		0.00 <		0.12	
HBC: M	0.2-1 (10 ³ /MM3)	10/05/91	0.48		0.21		0.25	
HBC: B	0-0.1 (10 ³ /MM3)	10/05/91	0.02		0.00		0.03	
PLATELETS	115-400 (10 ³ /UL)	10/05/91	158.00		142.00		220.00	
NA+	135-145 (MMOL/L)	10/05/91	140.00		139.00		137.00	
K+	3.8-4.8 (MMOL/L)	10/05/91	3.50 <		3.30 <		4.00	
CL-	98-108 (MMOL/L)	10/05/91	106.00		102.00		104.00	
Ca++	2.2-2.6 (MMOL/L)	10/05/91	2.11 <		2.16 <		2.14 <	
PO4--	0.8-1.4 (MMOL/L)	10/05/91	1.14		1.04		1.00	
SGOT	10-45 (U/L)	10/05/91	19.00		21.00		15.00	
SGPT	10-45 (U/L)	10/05/91	14.00		22.00		10.00	
GAMMA GT	5-45 (U/L)	10/05/91	10.00		14.00		11.00	
LDH	210-450 (UI/L)	10/05/91	322.00		356.00			
ALK. PHOSPH.	40-110 (U/L)	10/05/91	55.00		60.00		60.00	
GLUCOSE	4.5-5 (MMOL/L)	10/05/91	4.10 <		3.60 <		4.30 <	
UREA	3.5-7.5 (MMOL/L)	10/05/91	3.60		3.10 <		3.40 <	
CREATININE	45-90 (UMOL/L)	10/05/91	80.00		81.00		79.00	
URIC ACID	150-360 (UMOL/L)	10/05/91	138.00 <					
TOT BILIRUBIN	4-20 (UMOL/L)	10/05/91	6.00		5.00		3.90 <	
DIR BILIRUBIN	0-20 (UMOL/L)	10/05/91	4.00		1.00		0.70	
TOT. PROTEINS	60-75 (G/L)	10/05/91	71.00		70.00		67.00	
ALBUMINE	30.6-50.2 (G/L)	10/05/91	37.90					
TOT. CHOLEST.	4-6 (MMOL/L)	10/05/91	5.49		5.01			
TRIGLYCERIDES	0.5-1.5 (MMOL/L)	10/05/91	0.85		0.83			
GLOBULINS ALPHA 1	1.8-3.7 (G/L)	10/05/91	2.90					
GLOBULINS ALPHA 2	4.2-9 (G/L)	10/05/91	10.00 >					
GLOBULINS BETA	6-12 (G/L)	10/05/91	10.00					
GLOBULINS GAMMA	6-13 (G/L)	10/05/91	9.90					

1646

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/2 Patient: 45 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/08/91		30/09/91		21/10/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	27/07/91	13.20				12.70	
HT	38-48 (X)	27/07/91	42.00		45.00		40.40	
RBC	3.8-5.8 (10 ⁶ /UL)	27/07/91	4.62				4.48	
WBC	4-10 (10 ³ /UL)	27/07/91	8.43				7.84	
WBC: N	45-74 (X)	27/07/91	64.50				60.10	
WBC: L	16-45 (X)	27/07/91	27.30				31.50	
WBC: E	0-7 (X)	27/07/91	1.00				1.20	
WBC: M	4-10 (X)	27/07/91	3.60	<			4.00	
WBC: B	0-2 (X)	27/07/91	0.80				0.80	
PLATELETS	130-400 (10 ³ /UL)	27/07/91	241.00				218.00	
Na+	135-145 (MMOL/L)	27/07/91	138.00		138.00		140.00	
K+	3.5-4.8 (MMOL/L)	27/07/91	4.00				4.20	
CL-	96-108 (MMOL/L)	27/07/91	103.00		98.00		104.00	
Ca++	2.2-2.5 (MMOL/L)	27/07/91	2.25		2.29		2.09	<
PO4--	0.8-1.4 (MMOL/L)	27/07/91	0.87		0.90		0.96	<
SGOT	10-45 (UI/L)	27/07/91	18.00		20.00		18.00	
SGPT	10-65 (UI/L)	27/07/91	16.00		19.00		18.00	
GAMMA GT	5-45 (UI/L)	27/07/91	11.00		14.00		10.00	
LDH	210-450 (UI/L)	27/07/91	97.00		367.00		328.00	
ALK. PHOSPH.	40-130 (UI/L)	27/07/91	97.00		91.00		80.00	
GLUCOSE	3.5-5.5 (MMOL/L)	27/07/91	5.00		3.20	<	4.70	
BUN	()	27/07/91						
UREA	2.5-7.5 (MMOL/L)	27/07/91	2.60		4.60			
CREATININE	50-130 (UMOL/L)	27/07/91	88.00		85.00		66.00	
URIC ACID	150-360 (UMOL/L)	27/07/91			376.00	>	266.00	
TOT BILIRUBIN	0-17 (UMOL/L)	27/07/91	11.50		6.80		8.40	
DIR BILIRUBIN	0.2-5 (UMOL/L)	27/07/91			1.90		2.00	
TOT. PROTEINS	60-75 (G/L)	27/07/91	78.00	>	81.00	>	75.00	
ALBUMINE	35-50 (G/L)	27/07/91	47.00		46.00		42.00	
TOT. CHOLEST.	4-6.5 (MMOL/L)	27/07/91			6.23		4.92	
TRIGLYCERIDES	0.6-1.7 (MMOL/L)	27/07/91			2.34	>>	1.03	
GLOBULINS ALPHA 1	2-4 (X)	27/07/91			3.60		2.60	
GLOBULINS ALPHA 2	6-10 (X)	27/07/91			7.40		4.80	<
GLOBULINS BETA	8-12 (X)	27/07/91			13.70	>	10.00	
GLOBULINS GAMMA	11-19 (X)	27/07/91			15.20		11.80	
TSH	0.3-6.2 (MUI/L)	27/07/91	0.70					
T4	58-154 (NMOL/L)	27/07/91	73.00					

1647

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/2 Patient: 46 Treatment: Placebo Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			18/09/91		23/10/91	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	11.5-17 (G/DL)	01/09/91	12.90		12.90	
HT	38-48 (X)	01/09/91	39.50		39.80	
RBC	3.8-5.8 (10 ⁶ /UL)	01/09/91	4.10		4.14	
WBC	4-10 (10 ³ /UL)	01/09/91	9.80		8.22	
WBC: N	1.9-7.5 (10 ³ /UL)	01/09/91	5.96			
	45-74 (X)	20/10/91			59.40	
WBC: L	1.5-4 (10 ³ /UL)	01/09/91	3.09			
	16-45 (X)	20/10/91			31.70	
WBC: E	0-0.5 (10 ³ /UL)	01/09/91	0.18			
	0-7 (X)	20/10/91			1.90	
WBC: M	0.16-1 (10 ³ /UL)	01/09/91	0.32			
	4-10 (X)	20/10/91			3.60 <	
WBC: B	0-0.2 (10 ³ /UL)	01/09/91	0.03			
	0-2 (X)	20/10/91			0.90	
PLATELETS	130-400 (10 ³ /UL)	01/09/91	381.00		331.00	
NA+	135-145 (MMOL/L)	01/09/91	140.00		140.00	
K+	3.8-4.8 (MMOL/L)	01/09/91	3.70 <		3.20 <<	
CL-	96-108 (MMOL/L)	01/09/91	102.00		99.00	
Ca++	2.2-2.5 (MMOL/L)	01/09/91	2.17 <		2.19 <	
PO4--	0.8-1.4 (MMOL/L)	01/09/91	1.22		1.12	
SGOT	10-45 (UI/L)	01/09/91	14.00		16.00	
SGPT	10-65 (UI/L)	01/09/91	13.00		15.00	
GAMMA GT	5-45 (UI/L)	01/09/91	14.00		15.00	
LDH	210-450 (UI/L)	01/09/91	263.00		301.00	
ALK. PHOSPH.	40-130 (UI/L)	01/09/91	49.00		51.00	
GLUCOSE	3.5-5.5 (MMOL/L)	01/09/91	4.40		4.40	
UREA	2.5-7.5 (MMOL/L)	01/09/91	5.20			
CREATININE	50-130 (UMOL/L)	01/09/91	66.00			
	50-130 (MMOL/L)	20/10/91			62.00	
URIC ACID	150-360 (UMOL/L)	01/09/91	238.00		202.00	
	150-360 (MMOL/L)	20/10/91				
TOT BILIRUBIN	0-17 (UMOL/L)	01/09/91	9.50			
	0-17 (MMOL/L)	20/10/91			6.70	
DIR BILIRUBIN	0.2-5 (UMOL/L)	01/09/91	1.80			
	0.2-5 (MMOL/L)	20/10/91			1.80	
TOT. PROTEINS	60-75 (G/L)	01/09/91	72.00		69.00	
ALBUMINE	35-50 (G/L)	01/09/91	44.00		43.00	
TOT. CHOLEST.	4-6.5 (MMOL/L)	01/09/91	4.44		4.50	
TRIGLYCERIDES	0.5-1.5 (MMOL/L)	01/09/91	0.63		0.53	
GLOBULINS ALPHA 1	1.8-3.7 (G/L)	20/10/91			1.90	
GLOBULINS ALPHA 2	4.2-9 (G/L)	20/10/91			4.60	
GLOBULINS BETA	6-12 (G/L)	20/10/91			7.30	
GLOBULINS GAMMA	6-13 (G/L)	20/10/91			9.10	
TSH	0.3-6.2 (MUI/L)	01/09/91	0.60			
T4	58-154 (NMOL/L)	01/09/91	82.00			

1648

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/2 Patient: 47 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/03/92		14/04/92		05/05/92	
			value	(+)	value	(+)	value	(+)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/03/92	11.70		12.30		12.50	
HT	38-48 (X)	01/03/92	34.10 <		39.40		39.30	
RBC	3.8-5.8 (10 ⁶ /UL)	01/03/92	3.95		4.33		4.36	
HBC	4-10 (10 ³ /UL)	01/03/92	10.70 >		8.09		7.85	
HBC: N	1.9-7.5 (10 ³ /UL)	01/03/92	7.67 >					
	45-74 (X)	10/04/92			60.00		54.30	
HBC: L	1.5-4 (10 ³ /UL)	01/03/92	2.19					
	16-45 (X)	10/04/92			31.70		34.80	
HBC: E	0-0.5 (10 ³ /UL)	01/03/92	0.05					
	0-7 (X)	10/04/92			1.20		1.90	
HBC: M	0.16-1 (10 ³ /UL)	01/03/92	0.56					
	4-10 (X)	10/04/92			4.50		6.20	
HBC: B	0-0.2 (10 ³ /UL)	01/03/92	0.04					
	0-2 (X)	10/04/92			0.40		0.50	
PLATELETS	130-400 (10 ³ /UL)	01/03/92	253.00		192.00		181.00	
NA+	135-145 (MMOL/L)	01/03/92	138.00		141.00		135.00	
K+	3.5-4.8 (MMOL/L)	01/03/92	4.10		3.90		3.60	
CL-	96-108 (MMOL/L)	01/03/92	101.00		109.00 >		104.00	
Ca++	2.2-2.5 (MMOL/L)	01/03/92	2.29		1.96 <		2.26	
PO4--	0.8-1.4 (MMOL/L)	01/03/92	1.03		1.00		1.01	
SGOT	10-45 (UI/L)	01/03/92	16.00		25.00			
SGPT	10-65 (UI/L)	01/03/92	22.00		32.00			
GAMMA GT	5-45 (UI/L)	01/03/92	19.00		15.00			
ALK. PHOSPH.	40-130 (UI/L)	01/03/92	62.00		46.00			
GLUCOSE	3.5-5.5 (MMOL/L)	01/03/92	5.20		6.40 >		5.50	
UREA	2.5-7.5 (MMOL/L)	01/03/92	3.70					
	2.5-7.5 (MMOL/L)	10/04/92			6.80		4.10	
CREATININE	50-130 (MMOL/L)	01/03/92	62.00		73.00		74.00	
URIC ACID	150-360 (UMOL/L)	01/03/92	200.00					
TOT BILIRUBIN	0-17 (UMOL/L)	01/03/92	6.50					
	0-17 (MMOL/L)	10/04/92			10.40			
DIR BILIRUBIN	0.2-5 (UMOL/L)	01/03/92	0.90					
	0.2-5 (MMOL/L)	10/04/92			2.30			
TOT. PROTEINS	60-75 (G/L)	01/03/92	75.00		78.00 >		71.00	
ALBUMINE	35-50 (G/L)	01/03/92	49.00		52.00 >		48.00	
TOT. CHOLEST.	4-6.5 (MMOL/L)	01/03/92	4.71		5.60			
TRIGLYCERIDES	0.6-1.7 (MMOL/L)	01/03/92	0.66		0.42 <			
GLOBULINS ALPHA 1	1.8-3.7 (G/L)	01/03/92	3.20		2.80			
GLOBULINS ALPHA 2	4.2-9 (G/L)	01/03/92	9.00		7.60			
GLOBULINS BETA	6-12 (G/L)	01/03/92	7.60		13.10 >			
GLOBULINS GAMMA	6-13 (G/L)	01/03/92	10.10		13.80 >			
TSH	0.3-6.2 (MUI/L)	01/03/92	0.60					
T4	10-23 (PMOL/L)	01/03/92	15.10					

1649

(+) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/2 Patient: 48 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/04/92		28/04/92		20/05/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/03/92	12.20		12.60			
HT	38-48 (X)	01/03/92	38.70		39.00			
RBC	3.8-5.8 (10 ⁶ /UL)	01/03/92	4.09		4.23			
MBC	4-10 (10 ³ /UL)	01/03/92	7.34		7.16			
MBC: N	45-74 (%)	01/03/92	62.80		58.90			
MBC: L	16-45 (%)	01/03/92	26.80		29.70			
MBC: E	0-7 (%)	01/03/92	2.40		2.50			
MBC: M	4-10 (%)	01/03/92	4.50		5.20			
MBC: B	0-2 (%)	01/03/92	0.60		0.50			
PLATELETS	130-400 (10 ³ /UL)	01/03/92	289.00		285.00			
NA+	135-145 (MMOL/L)	01/03/92	137.00		136.00			
K+	3.5-4.8 (MMOL/L)	01/03/92	3.80		4.80			
CL-	96-108 (MMOL/L)	01/03/92	105.00		103.00			
Ca++	2.2-2.5 (MMOL/L)	01/03/92	2.22		2.29			
PO4--	0.8-1.4 (MMOL/L)	01/03/92	0.77 <		0.93			
SGOT	10-45 (UI/L)	01/03/92	13.00		17.00	17.00		
SGPT	10-65 (UI/L)	01/03/92	11.00		13.00	13.00		
GAMMA GT	5-45 (UI/L)	01/03/92	19.00		13.00			
ALK. PHOSPH.	40-130 (UI/L)	01/03/92	45.00		66.00	65.00		
GLUCOSE	3.5-5.5 (MMOL/L)	01/03/92			4.80			
UREA	2.5-7.5 (MMOL/L)	01/03/92	4.40		4.30			
CREATININE	50-130 (MMOL/L)	01/03/92			71.00			
URIC ACID	150-360 (MMOL/L)	01/03/92	318.00			413.00 >		
TOT BILIRUBIN	0-17 (MMOL/L)	01/03/92	10.70		10.90	10.30		
DIR BILIRUBIN	0.2-5 (MMOL/L)	01/03/92	4.30		2.70	2.70		
TOT. PROTEINS	60-75 (G/L)	01/03/92	70.00		76.00 >			
ALBUMINE	35-50 (G/L)	01/03/92	46.00		53.00 >			
TOT. CHOLEST.	4-6.5 (MMOL/L)	01/03/92	4.55		4.21	4.21		
TRIGLYCERIDES	0.6-1.7 (MMOL/L)	01/03/92			0.52 <	0.52 <		
TSH	0.3-6.2 (MUI/L)	01/03/92	3.40					
T4	10-23 (PMOL/L)	01/03/92	13.50					

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1650

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/3 Patient: 36/A Treatment: Imipramine Sex: Male

			Visit number / Laboratory date			
			Day 21		Day 42	
			22/03/91		08/04/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	12-14 (GR/DL)	06/02/91	16.50 >			
HT	32-47 (X)	06/02/91	51.30 >			
RBC	4-5.4 (10 ⁶ /UL)	06/02/91	5.59 >			
MBC	5-10 (10 ³ /UL)	06/02/91	8.80			
MBC: N	52-68 (X)	06/02/91	73.00 >			
MBC: L	26-38 (X)	06/02/91	23.00 <			
MBC: E	1-3 (X)	06/02/91	1.00			
MBC: M	4-8 (X)	06/02/91	3.00 <			
MBC: B	0-1 (X)	06/02/91	0.00			
PLATELETS	150-450 (10 ³ /UL)	06/02/91	299.00			
NA+	135-145 (MEQ/L)	06/02/91	140.00	137.00		
K+	3.5-5.5 (MEQ/L)	06/02/91	5.00	4.80		
CL-	98-107 (MEQ/L)	06/02/91	102.00	98.00		
Ca++	88-102 (MG/L)	06/02/91	101.00	98.00		
PO4--	25-50 (MG/L)	06/02/91	36.00	41.00		
SGOT	5-22 (U/L)	06/02/91	16.00	17.00		
SGPT	5-24 (U/L)	06/02/91	12.00	14.00		
GAMMA GT	5-29 (U/L)	06/02/91	13.00	13.00		
LDH	160-230 (U/L)	06/02/91	215.00	540.00 >>		
ALK. PHOSPH.	30-100 (U/L)	06/02/91	43.00	43.00		
GLUCOSE	0.5-1.1 (G/L)	06/02/91	1.44 >>	1.48 >>		
UREA	0.2-0.45 (G/L)	06/02/91	0.28	0.28		
CREATININE	6-13 (MG/L)	06/02/91	11.00	9.40		
URIC ACID	30-60 (MG/L)	06/02/91	65.00 >	70.00 >		
TOT BILIRUBIN	1.5-10 (MG/L)	06/02/91	5.00	3.00		
DIR BILIRUBIN	0-3 (MG/L)	06/02/91	4.00 >			
TOT. PROTEINS	60-80 (G/L)	06/02/91	69.00	67.00		
ALBUMINE	34-48 (G/L)	06/02/91	39.70	36.30		
TOT. CHOLEST.	1.5-2.4 (G/L)	06/02/91	2.85 >	3.06 >		
TRIGLYCERIDES	0.5-1.5 (G/L)	06/02/91	2.20 >>	2.75 >>		
GLOBULINS ALPHA 1	1-3 (G/L)	06/02/91	2.40	2.40		
GLOBULINS ALPHA 2	4-7 (G/L)	06/02/91	10.00 >>	11.30 >>		
GLOBULINS BETA	6-11 (G/L)	06/02/91	10.30	9.50		
GLOBULINS GAMMA	8-14 (G/L)	06/02/91	6.30 <	7.10 <		

1651

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/3 Patient: 37 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 42	
			18/03/91		13/05/91	
			value	(†)	value	(†)
Laboratory test	Range value	Range date				
HB	12-16 (G/L)	01/03/91	14.00			
HT	35-45 (X)	01/03/91	44.00			
RBC	4-5 (10 ⁶ /UL)	01/03/91	4.66			
HBC	4-10 (10 ³ /UL)	01/03/91	6.40			
HBC: N	50-70 (X)	01/03/91	66.00			
HBC: L	20-40 (X)	01/03/91	27.00			
HBC: E	0-3 (X)	01/03/91	3.00			
HBC: M	2-8 (X)	01/03/91	4.00			
HBC: B	0-2 (X)	01/03/91	0.00			
PLATELETS	150-400 (10 ³ /UL)	01/03/91	247.00			
NA+	135-143 (MEQ/L)	01/03/91	137.00		139.00	
K+	3.5-5.5 (MEQ/L)	01/03/91	3.80		3.80	
CL-	97-108 (MEQ/L)	01/03/91	99.00		98.00	
Ca++	86-108 (MEQ/L)	01/03/91	91.00		90.00	
PO4--	28-42 (MG/L)	01/03/91	51.00	>>	42.00	
SGOT	5-25 (UI/L)	01/03/91	28.00	>	23.00	
SGPT	5-25 (UI/L)	01/03/91	14.00		12.00	
GAMMA GT	5-30 (UI/L)	01/03/91	32.00	>	16.00	
LDH	150-320 (UI/L)	01/03/91	216.00		192.00	
ALK. PHOSPH.	50-200 (UI/L)	01/03/91	143.00		122.00	
GLUCOSE	0.7-1.1 (G/L)	01/03/91	0.97		0.92	
UREA	0.15-0.4 (G/L)	01/03/91	0.23		0.25	
CREATININE	6-12 (MG/L)	01/03/91	10.00		11.00	
URIC ACID	20-60 (MG/L)	01/03/91	34.00		50.00	
TOT BILIRUBIN	1.5-10 (MG/L)	01/03/91	9.00		4.00	
TOT. PROTEINS	62-75 (G/L)	01/03/91	68.00		72.00	
ALBUMINE	40-60 (G/L)	01/03/91	42.16		44.64	
TOT. CHOLEST.	2-2.5 (G/L)	01/03/91	3.26	>>	3.16	>
TRIGLYCERIDES	0.45-1.5 (G/L)	01/03/91	1.89	>	3.79	>>
GLOBULINS ALPHA 1	2-5 (X)	01/03/91	2.00		3.00	
GLOBULINS ALPHA 2	4-12 (X)	01/03/91	9.00		10.00	
GLOBULINS BETA	9-15 (X)	01/03/91	13.00		12.00	
GLOBULINS GAMMA	14-20 (X)	01/03/91	14.00		13.00	<

1652

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/3 Patient: 38 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/08/91		09/09/91		26/09/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-17 (G/DL)	25/07/91	15.50		15.40		15.80	
HT	35-54 (%)	25/07/91	44.20		40.00		45.90	
RBC	4-5.5 (10 ⁶ /UL)	25/07/91	4.97		4.51		5.20	
WBC	4-9 (10 ³ /UL)	25/07/91	7.50		8.30		7.20	
WBC: N	52-68 (%)	25/07/91	67.00		61.00		66.00	
WBC: L	26-38 (%)	25/07/91	25.00	<	32.00		26.00	
WBC: E	1-3 (%)	25/07/91	2.00		2.00		2.00	
WBC: M	4-8 (%)	25/07/91	6.00		5.00		6.00	
WBC: B	0-1 (%)	25/07/91	0.00		0.00		0.00	
PLATELETS	200-400 (10 ³ /UL)	25/07/91	259.00		257.00		307.00	
NA+	137-146 (MEQ/L)	25/07/91	139.00		139.00		140.00	
K+	3.8-5.2 (MEQ/L)	25/07/91	3.70	<	3.70	<	3.70	
CL-	95-106 (MEQ/L)	25/07/91	101.00		102.00		100.00	
Ca++	90-104 (MG/L)	25/07/91	92.00		94.00		92.00	
PO4--	25-42 (MG/L)	25/07/91	30.00		36.00		37.00	
SGOT	5-25 (UI/L)	25/07/91	8.00		9.00		10.00	
SGPT	5-29 (UI/L)	25/07/91	17.00		15.00		19.00	
GAMMA GT	7-34 (UI/L)	25/07/91	23.00		11.00		26.00	
LDH	140-280 (UI/L)	25/07/91	194.00		201.00		195.00	
ALK. PHOSPH.	30-100 (UI/L)	25/07/91	60.00		59.00		58.00	
GLUCOSE	0.7-1.1 (G/L)	25/07/91	0.91		0.89		0.91	
UREA	0.15-0.5 (G/L)	25/07/91	0.28		0.24		0.21	
CREATININE	5-12 (MG/L)	25/07/91	12.40	>	9.80		11.20	
URIC ACID	34-70 (MG/L)	25/07/91	44.00		62.00		66.00	
TOT. BILIRUBIN	1.5-10 (MG/L)	25/07/91	9.60		11.70	>	7.70	
TOT. PROTEINS	65-87 (G/L)	25/07/91			74.00		73.00	
ALBUMINE	57-65 (%)	25/07/91			62.60		59.00	
TOT. CHOLEST.	1.2-2.4 (G/L)	25/07/91	2.48	>	2.39		2.56	
TRIGLYCERIDES	0.4-1.5 (G/L)	25/07/91	1.23		2.15	>>	2.46	
GLOBULINS ALPHA 1	2-4 (%)	25/07/91			3.90		3.30	
GLOBULINS ALPHA 2	6-10 (%)	25/07/91			6.40		6.60	
GLOBULINS BETA	8-12 (%)	25/07/91			9.80		10.40	
GLOBULINS GAMMA	12-19 (%)	25/07/91			17.30		20.60	

1653

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value φ laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/3 Patient: 39 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			06/08/91		30/08/91	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	12.5-15 (G/DL)	01/08/91	13.50			
HT	36-45 (X)	01/08/91	40.60			
RBC	3.8-5 (10 ⁶ /UL)	01/08/91	4.72			
WBC	6.7-10 (10 ³ /UL)	01/08/91	6.70			
WBC: N	52-68 (X)	01/08/91	60.00			
WBC: L	26-38 (X)	01/08/91	35.00			
WBC: E	1-3 (X)	01/08/91	1.00			
WBC: M	4-8 (X)	01/08/91	4.00			
WBC: B	0-1 (X)	01/08/91	0.00			
PLATELETS	200000-450000 (/UL)	01/08/91	344000			
NA+	137-145 (MMOL/L)	01/08/91	140.00	139.00		
K+	3.7-5 (MMOL/L)	01/08/91	3.80	3.80		
CL-	90-110 (MMOL/L)	01/08/91	100.00	99.00		
Ca++	85-104 (MG/L)	01/08/91	103.00	96.40		
PO4--	25-42 (MG/L)	01/08/91	42.20	33.60		
SGOT	5-22 (U/L)	01/08/91	10.00	7.00		
SGPT	5-24 (U/L)	01/08/91	12.00	11.00		
GAMMA GT	6-22 (U/L)	01/08/91	13.00	14.00		
LDH	140-280 (UI/L)	01/08/91	237.00	252.00		
ALK. PHOSPH.	30-100 (UI/L)	01/08/91	45.00			
GLUCOSE	0.75-1.1 (G/L)	01/08/91	1.09			
UREA	0.15-0.4 (G/L)	01/08/91	0.41	0.25		
CREATININE	6.8-12.4 (MG/L)	01/08/91	8.90	9.60		
URIC ACID	24-57 (MG/L)	01/08/91	36.70	39.00		
TOT. BILIRUBIN	3-11 (MG/L)	01/08/91	3.40	3.40		
TOT. PROTEINS	60-80 (G/L)	01/08/91	76.70	72.80		
ALBUMINE	32-50 (G/L)	01/08/91	49.10	46.80		
TOT. CHOLEST.	1.5-2.4 (G/L)	01/08/91	3.27	2.69		
TRIGLYCERIDES	0.6-1.5 (G/L)	01/08/91	0.88	0.70		
GLOBULINS ALPHA 1	1-4 (G/L)	01/08/91	2.40			
	1.5-4.5 (X)	15/08/91		3.20		
GLOBULINS ALPHA 2	5-11 (G/L)	01/08/91	6.50			
	6-12 (X)	15/08/91		10.30		
GLOBULINS BETA	6-13 (G/L)	01/08/91	9.60			
	11-17 (X)	15/08/91		10.90		
GLOBULINS GAMMA	7-15 (G/L)	01/08/91	9.10			
	11-19 (X)	15/08/91		9.20		

1654

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/3 Patient: 40 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/10/91		15/11/91		05/12/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/10/91	15.00		11.60	<	13.00	
HT	35-52 (X)	01/10/91	43.00		34.70	<	38.10	
RBC	4-6 (10 ⁶ /UL)	01/10/91	4.16		3.33	<<	3.62	
RBC	4-10 (10 ³ /UL)	01/10/91	4.80		8.20		8.10	
RBC: N	50-76 (%)	01/10/91	53.00		56.00		70.00	
RBC: L	15-45 (%)	01/10/91	42.00		38.00		20.00	
RBC: E	0-5 (%)	01/10/91	1.00		3.00		0.00	
RBC: M	4-9.9 (%)	01/10/91	4.00		3.00	<	8.00	
RBC: B	0-3 (%)	01/10/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/10/91	184.00		327.00		285.00	
NA+	137-145 (MMOL/L)	01/10/91	133.00	<	140.00		142.00	
K+	3.3-5 (MMOL/L)	01/10/91	3.70		4.70		5.60	
CL-	98-106 (MMOL/L)	01/10/91	90.00	<	100.00		101.00	
Ca++	2.2-2.6 (MMOL/L)	01/10/91	2.30		2.20		2.37	
PO4--	0.8-1.3 (MMOL/L)	01/10/91	1.13		1.12		1.39	
SGOT	0-0.4 (UKAT/L)	01/10/91	1.40	>>	0.30		0.40	
SGPT	0-0.4 (UKAT/L)	01/10/91	0.70	>	0.10		0.70	
GAMMA GT	0.1-0.4 (UKAT/L)	01/10/91	3.20	>>	0.90	>>	0.90	
LDH	2.4-5.5 (UKAT/L)	01/10/91	3.50		3.70		3.60	
ALK. PHOSPH.	0.5-1.7 (UKAT/L)	01/10/91	1.40		0.90		1.20	
GLUCOSE	4-6 (MMOL/L)	01/10/91	4.10		3.90	<	4.90	
UREA	3-6.5 (MMOL/L)	01/10/91	1.60	<	2.80	<	2.10	
CREATININE	45-90 (UMOL/L)	01/10/91	54.00		47.00		53.00	
URIC ACID	150-360 (UMOL/L)	01/10/91	130.00	<	129.00	<	162.00	
TOT BILIRUBIN	0-17 (UMOL/L)	01/10/91	12.00		4.00		9.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/10/91	3.00		2.00		3.00	
TOT. PROTEINS	38.7-48.8 (G/L)	01/10/91	56.00	>				
	65-80 (G/L)	14/11/91			51.00	<	53.00	
ALBUMINE	57-69 (X)	01/10/91	61.00		64.00		55.50	
TOT. CHOLEST.	3.2-6.3 (MMOL/L)	01/10/91	7.40	>	9.20	>>	10.20	
TRIGLYCERIDES	0.4-1.4 (MMOL/L)	01/10/91	1.30		3.50	>>	2.50	
GLOBULINS ALPHA 1	1-3 (G/L)	01/10/91	2.60					
	2-4 (X)	14/11/91			3.70		4.30	
GLOBULINS ALPHA 2	4-10 (G/L)	01/10/91	4.40					
	6-10 (X)	14/11/91			9.20		9.80	
GLOBULINS BETA	5-11 (G/L)	01/10/91	5.30					
	7-12 (X)	14/11/91			10.20		13.10	
GLOBULINS GAMMA	8-16 (G/L)	01/10/91	9.50					
	10-20 (X)	14/11/91			12.90		17.30	
TSH	0.2-35 (UU/ML)	01/10/91	1.60					
	0.2-3.5 (UU/ML)	14/11/91					16.00	
T4	7.3-20.1 (PG/ML)	01/10/91	14.00				12.00	

1655

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/3 Patient: 41 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/10/91		29/10/91		19/11/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/10/91	14.00		13.30		13.70	
BT	38-52 (%)	01/10/91	42.00		41.00		41.00	
RBC	4.2-5.7 (10 ⁶ /UL)	01/10/91	4.78		4.60		4.30 >	
WBC	4-10 (10 ³ /UL)	01/10/91	11.90 >		9.20		4.50	
WBC: N	2-7 (10 ³ /UL)	01/10/91	8.33 >		5.06		5.31	
WBC: L	1-4 (10 ³ /UL)	01/10/91	3.09		3.40		2.41	
WBC: E	40-300 (/UL)	01/10/91	119.00		184.00		166.00	
WBC: M	20-800 (/UL)	01/10/91	357.00		552.00		415.00	
WBC: B	0-100 (/UL)	01/10/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/10/91	151.00		206.00		202.00	
NA+	137-146 (MEQ/L)	01/10/91	139.00		140.00		140.00	
K+	3.7-5 (MEQ/L)	01/10/91	3.80		3.90		3.70	
CL-	96-106 (MEQ/L)	01/10/91	100.00		107.00 >		109.00 >	
Ca++	92-105 (MG/L)	01/10/91	100.00		98.00		95.00	
PO4--	25-42 (MG/L)	01/10/91	50.00 >>		41.00		42.00	
SGOT	5-27 (UI/L)	01/10/91	30.00 >		14.00		12.00	
SGPT	5-30 (UI/L)	01/10/91	42.00 >		23.00		16.00	
GAMMA GT	5-38 (UI/L)	01/10/91	50.00 >		32.00		19.00	
LDH	160-320 (UI/L)	01/10/91	196.00		169.00		162.00	
ALK. PHOSPH.	30-90 (UI/L)	01/10/91	47.00		37.00		40.00	
GLUCOSE	0.7-1.1 (G/L)	01/10/91	0.98		0.99		1.03	
UREA	0.15-0.45 (G/L)	01/10/91	0.34		0.45		0.32	
CREATININE	6-15 (MG/L)	01/10/91	6.00		8.00		7.00	
URIC ACID	30-79 (MG/L)	01/10/91	70.00		60.00		60.00	
TOT BILIRUBIN	1.5-10 (MG/L)	01/10/91	4.00		3.00		2.80	
TOT. PROTEINS	65-75 (G/L)	01/10/91	65.00		71.00		72.00	
ALBUMINE	35-52 (G/L)	01/10/91	40.10		54.40 >		57.20 >	
TOT. CHOLEST.	1.3-2.3 (G/L)	01/10/91	2.57 >		2.77 >		2.16	
TRIGLYCERIDES	0.4-1.5 (G/L)	01/10/91	2.42 >>		2.41 >>		3.36 >>	
GLOBULINS ALPHA 1	1-4 (%)	01/10/91	3.50		4.30 >		3.70	
GLOBULINS ALPHA 2	6-10 (%)	01/10/91	8.50		9.00		9.80	
GLOBULINS BETA	8-12 (%)	01/10/91	13.50 >		16.70 >>		14.80 >	
GLOBULINS GAMMA	13-19 (%)	01/10/91	12.70 <		14.90		14.50	
TSH	0.2-5 (MUI/L)	01/10/91	0.67				1.02	
T4	6.2-50 (PG/ML)	01/10/91	14.80				12.70	

1656

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/3 Patient: 42 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/05/92		06/06/92		30/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	05/03/92	12.50					
	13-16 (G/DL)	05/06/92		11.80 <		12.30 <		
HT	35-52 (X)	05/03/92	37.10		35.00		38.40	
	32-47 (X)	05/06/92						
RBC	4-6 (10 ⁶ /UL)	05/03/92	3.90 <					
	4-5.2 (10 ⁶ /UL)	05/06/92		3.71 <		4.02		
HBC	4-10 (10 ³ /UL)	05/03/92	3.80 <		8.70		8.10	
	4.5-9 (10 ³ /UL)	05/06/92						
HBC: N	50-76 (X)	05/03/92	37.20 <					
	50-70 (X)	05/06/92		74.00 >		67.00		
HBC: L	15-45 (X)	05/03/92	47.60 >					
	25-40 (X)	05/06/92		17.00 <<		29.00		
HBC: E	0-5 (X)	05/03/92	0.50					
	1-4 (X)	05/06/92		3.00		1.00		
HBC: N	4-9.9 (X)	05/03/92	13.70 >>					
	4-10 (X)	05/06/92		5.00		3.00 <		
HBC: B	0-3 (X)	05/03/92	1.00					
	0-1 (X)	05/06/92		1.00		0.00		
PLATELETS	150-400 (10 ³ /UL)	05/03/92	504.00 >		362.00		470.00 >	
NA+	137-145 (MMOL/L)	05/03/92	138.00					
	135-145 (MEQ/L)	05/06/92		140.00		142.00		
K+	3.3-5 (MMOL/L)	05/03/92	3.90					
	3.7-5.2 (MEQ/L)	05/06/92		3.60 <		4.80		
CL-	98-106 (MMOL/L)	05/03/92	104.00					
	97-109 (MEQ/L)	05/06/92		102.00		105.00		
Ca++	2.2-2.6 (MMOL/L)	05/03/92	2.34					
	95-105 (MG/L)	05/06/92		90.00 <		87.00 <		
PO4--	0.8-1.3 (MMOL/L)	05/03/92	0.70 <					
	28-45 (MG/L)	05/06/92		21.00 <<		24.00 <		
SGOT	0-0.4 (UKAT/L)	05/03/92	0.20					
	5-37 (UI/L)	05/06/92		13.00		11.00		
SGPT	0-0.4 (UKAT/L)	05/03/92	0.10					
	5-40 (UI/L)	05/06/92		6.00		10.00		
GAMMA GT	0.1-0.4 (UKAT/L)	05/03/92	1.30 >>					
	7-32 (UI/L)	05/06/92		63.00 >		89.00 >>		
LDH	2.4-5.5 (UKAT/L)	05/03/92	3.50					
	230-460 (UI/L)	05/06/92		557.00 >		421.00		
ALK. PHOSPH.	0.5-1.7 (UKAT/L)	05/03/92	2.20 >					
	39-117 (UI/L)	05/06/92		134.00 >		142.00 >		
GLUCOSE	4-6 (MMOL/L)	05/03/92	6.20 >					
	0.8-1.1 (G/L)	05/06/92		1.08		0.93		
UREA	3-6.5 (MMOL/L)	05/03/92	4.20					
	0.15-0.4 (G/L)	05/06/92		0.24		0.17		
CREATININE	45-90 (UMOL/L)	05/03/92	93.00 >					
	5-12 (MG/L)	05/06/92		11.00		10.20		
URIC ACID	150-360 (UMOL/L)	05/03/92	234.00					
	30-70 (MG/L)	05/06/92		56.00		68.00		
TOT BILIRUBIN	0-17 (UMOL/L)	05/03/92	5.00					
	0-10 (MG/L)	05/06/92		1.00		5.00		
DIR BILIRUBIN	0-4 (UMOL/L)	05/03/92	2.00					
TOT. PROTEINS	65-80 (G/L)	05/03/92	72.00		67.00		71.00	
ALBUMINE	57-69 (G/L)	05/03/92	58.20					
	52-65 (X)	05/06/92		49.90 <		53.10		
TOT. CHOLEST.	3.2-6.3 (MMOL/L)	05/03/92	7.10 >					
	1.7-2.3 (G/L)	05/06/92		2.22		2.15		
TRIGLYCERIDES	0.4-1.4 (MMOL/L)	05/03/92	2.40 >>					
	0.5-1.5 (G/L)	05/06/92		1.91 >		2.05 >>		
GLOBULINS ALPHA 1	2-4 (X)	05/03/92	4.50 >					
	1-4.6 (X)	05/06/92		3.10		3.80		
GLOBULINS ALPHA 2	6-10 (X)	05/03/92	10.90 >					
	6-17.6 (X)	05/06/92		11.80		16.40		
GLOBULINS BETA	7-12 (X)	05/03/92	13.50 >					

(CONTINUED)

1657

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/3 Patient: 42 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/05/92		06/06/92		30/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
GLOBULINS BETA	8-15.7 (%)	05/06/92						
GLOBULINS GAMMA	10-20 (%)	05/03/92	13.50		10.50		15.10	
	8-12.2 (%)	05/06/92			8.20		11.60	
TSH	0.2-3.5 (UU/ML)	05/03/92	1.10					
T4	7.3-20.1 (PG/ML)	05/03/92	12.00					

1658

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/4 Patient: 31 Treatment: Placebo Sex: Male

			Visit number / Laboratory date	
			Screen	Day 42
			22/03/91	30/04/91
Laboratory test	Range value	Range date	value (†)	value (†)
HB	13-18 (G/DL)	02/03/91	15.80	15.30
HT	39-52 (X)	02/03/91	44.30	44.10
RBC	4.2-5.7 (10 ⁶ /UL)	02/03/91	4.56	4.50
MBC	5000-9000 (/UL)	02/03/91	12940.0 >>	9860.00 >
MBC: N	50-70 (X)	02/03/91	69.60	67.40
MBC: L	25-45 (X)	02/03/91	22.30 <	26.00
MBC: E	1-3 (X)	02/03/91	0.10 <	1.00
MBC: M	2-9 (X)	02/03/91	7.40	4.90
MBC: B	0-1 (X)	02/03/91	0.70	0.60
NA+	135-145 (MEQ/L)	02/03/91	137.00	140.00
K+	3.6-4.9 (MEQ/L)	02/03/91	4.60	4.70
CL-	95-105 (MEQ/L)	02/03/91	96.00	100.00
Ca++	95-105 (MG/L)	02/03/91	101.00	104.00
PO4--	25-48 (MG/L)	02/03/91	30.00	28.00
SGOT	10-41 (UI/L)	02/03/91	31.00	26.00
SGPT	10-41 (UI/L)	02/03/91	20.00	16.00
GAMMA GT	7-36 (UI/L)	02/03/91	39.00 >	49.00 >
LDH	220-440 (UI/L)	02/03/91	329.00	462.00 >
ALK. PHOSPH.	35-110 (UI/L)	02/03/91	51.00	39.00
GLUCOSE	4.45-6.12 (MMOL/L)	02/03/91	5.62	4.32 <
UREA	3.32-8.3 (MMOL/L)	02/03/91	4.29	3.15 <
CREATININE	61.95-115.05 (UMOL/L)	02/03/91	73.81	69.09
URIC ACID	136.9-416.5 (UMOL/L)	02/03/91	218.80	315.50
TOT BILIRUBIN	3-17.1 (UMOL/L)	02/03/91	1.29 <	3.04
DIR BILIRUBIN	0-4.28 (UMOL/L)	02/03/91	0.80	
TOT. PROTEINS	65-80 (G/L)	02/03/91	72.00	67.00
ALBUMINE	37-52 (G/L)	02/03/91	46.90	42.50
TOT. CHOLEST.	1.5-2.5 (G/L)	02/03/91	2.52 >	2.81 >
TRIGLYCERIDES	0.5-1.6 (G/L)	02/03/91	0.90	1.50
GLOBULINS ALPHA 1	2-4 (X)	02/03/91	3.20	3.50
GLOBULINS ALPHA 2	6-10 (X)	02/03/91	10.30 >	10.00
GLOBULINS BETA	8-12 (X)	02/03/91	10.00	11.80
GLOBULINS GAMMA	12-19 (X)	02/03/91	11.20 <	11.40 <
TSH	0.32-3.7 (MU/L)	02/03/91	0.79	
T4	8-20 (PMOL/L)	02/03/91	17.80	

1659

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/4 Patient: 32 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/10/91		15/11/91		06/12/91	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/01/91	14.10		14.00		15.20	
HT	39-52 (X)	01/01/91	43.90		40.90		46.50	
RBC	4.2-5.7 (10 ⁶ /UL)	01/01/91	4.58		4.52		4.94	
HBC	5000-9000 (/UL)	01/01/91	6840.00		7590.00		7430.00	
HBC: N	50-70 (X)	01/01/91	70.40	>	77.60	>	71.00	>
HBC: L	25-45 (X)	01/01/91	17.90	<	13.20	<<	17.30	<<
HBC: E	1-3 (X)	01/01/91	4.10	>>	2.30		3.60	>
HBC: M	2-9 (X)	01/01/91	6.80		6.40		6.90	
HBC: B	0-1 (X)	01/01/91	0.80		0.50		0.60	
PLATELETS	200000-400000 (/UL)	01/01/91	223000		228000		202000	
NA+	135-145 (MEQ/L)	01/01/91	143.00		140.00		138.00	
K+	3.6-4.9 (MEQ/L)	01/01/91	4.30		4.80		3.80	
CL-	95-105 (MEQ/L)	01/01/91	102.00		101.00		98.00	
Ca++	95-105 (MG/L)	01/01/91	100.00		98.00		97.00	
PO4--	25-48 (MG/L)	01/01/91	28.00		20.00	<<	33.00	
SGOT	10-41 (UI/L)	01/01/91	16.00		18.00		22.00	
SGPT	10-41 (UI/L)	01/01/91	19.00		21.00		23.00	
GAMMA GT	7-36 (UI/L)	01/01/91	35.00		31.00		38.00	>
LDH	220-440 (UI/L)	01/01/91	325.00		336.00		366.00	
ALK. PHOSPH.	35-110 (UI/L)	01/01/91	40.00		40.00		38.00	
GLUCOSE	0.8-1.1 (G/L)	01/01/91	0.80		0.75	<	0.90	
UREA	0.2-0.5 (G/L)	01/01/91	0.20		0.35		0.33	
CREATININE	7-13 (MG/L)	01/01/91	12.20		11.10		10.60	
URIC ACID	23-70 (MG/L)	01/01/91	71.00	>	64.00		68.00	
TOT BILIRUBIN	0-10 (MG/L)	01/01/91	3.40		3.20		3.80	
TOT. PROTEINS	65-80 (G/L)	01/01/91	77.00		71.00		71.00	
ALBUMINE	37-52 (G/L)	01/01/91	45.90		46.40		42.90	
TOT. CHOLEST.	1.5-2.5 (G/L)	01/01/91	1.57		1.69		1.48	<
TRIGLYCERIDES	0.5-1.6 (G/L)	01/01/91	1.17		0.84		0.76	
GLOBULINS ALPHA 1	1-3 (G/L)	01/01/91	2.00		1.80		2.00	
GLOBULINS ALPHA 2	4-7 (G/L)	01/01/91	8.50	>	5.70		7.30	>
GLOBULINS BETA	5-8 (G/L)	01/01/91	8.40	>	7.30		7.50	
GLOBULINS GAMMA	8-12 (G/L)	01/01/91	12.40	>	9.60		11.00	
TSH	0.32-3.7 (MU/L)	01/01/91	1.10					
T4	8-20 (PMOL/L)	01/01/91	12.70					

1660

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/4 Patient: 33 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 42
			27/05/91	10/07/91
			value (⊕)	value (⊕)
Laboratory test	Range value	Range date		
HB	13-18 (G/DL)	01/05/91	15.40	16.00
HT	39-52 (X)	01/05/91	43.90	48.00
RBC	4.2-5.7 (10 ⁶ /UL)	01/05/91	4.53	4.82
MBC	5000-9000 (/UL)	01/05/91	7290.00	6110.00
MBC: N	50-70 (X)	01/05/91	60.00	67.30
MBC: L	25-45 (X)	01/05/91	27.00	22.80
MBC: E	1-3 (X)	01/05/91	4.60 >>	3.50 >
MBC: M	2-9 (X)	01/05/91	7.00	5.40
MBC: B	0-1 (X)	01/05/91	1.00	0.90
PLATELETS	200000-400000 (/UL)	01/05/91	175000 <	154000 <
NA+	135-145 (MEQ/L)	01/05/91	140.00	142.00
K+	3.6-4.9 (MEQ/L)	01/05/91	4.20	4.40
CL-	95-105 (MEQ/L)	01/05/91	100.00	101.00
Ca++	95-105 (MG/L)	01/05/91	100.00	2.55
PO4---	2.38-2.63 (MMOL/L)	10/06/91		
	25-48 (MG/L)	01/05/91	41.00	
	0.8-1.54 (MMOL/L)	10/06/91		1.30
SCOT	10-41 (UI/L)	01/05/91	37.00	60.00 >
SEPT	10-41 (UI/L)	01/05/91	14.00	22.00
GAMMA GT	7-36 (UI/L)	01/05/91	266.00 >>	396.00 >>
LDH	220-440 (UI/L)	01/05/91	309.00	418.00
ALK. PHOSPH.	35-110 (UI/L)	01/05/91	54.00	79.00
GLUCOSE	4.45-6.12 (MMOL/L)	01/05/91	4.30 <	4.85
UREA	0.2-0.5 (G/L)	01/05/91	0.19 <	
	3.32-8.3 (MMOL/L)	10/06/91		2.29 <
CREATININE	7-13 (MG/L)	01/05/91	7.30	
	61.95-115.05 (UMOL/L)	10/06/91		56.72 <
URIC ACID	23-70 (MG/L)	01/05/91	62.00	
	136.9-416.5 (UMOL/L)	10/06/91		227.90
TOT BILIRUBIN	0-10 (MG/L)	01/05/91	6.50	
	3-17.1 (MMOL/L)	10/06/91		16.70
TOT. PROTEINS	65-80 (G/L)	01/05/91	67.00	80.00
ALBUMINE	37-52 (G/L)	01/05/91	44.30	48.70
TOT. CHOLEST.	1.5-2.5 (G/L)	01/05/91	1.95	
	3.87-6.45 (MMOL/L)	10/06/91		5.39
TRIGLYCERIDES	0.5-1.6 (G/L)	01/05/91	1.14	
	0.57-1.82 (MMOL/L)	10/06/91		1.35
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	1.40	2.20
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	5.30	8.30 >
GLOBULINS BETA	5-8 (G/L)	01/05/91	5.70	9.30 >
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	10.30	11.70
TSH	0.32-3.7 (MU/L)	01/05/91	3.27	
T4	8-20 (PMOL/L)	01/05/91	11.30	

1661

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/4 Patient: 34 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/04/92		12/05/92		25/05/92	
			value	(±)	value	(±)	value	(±)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/03/91	14.00		14.70		15.40	
HT	39-52 (%)	01/03/91	41.10		43.90		45.90	
RBC	4.2-5.7 (10 ⁶ /UL)	01/03/91	4.54		4.17 <		4.89	
WBC	5000-9000 (/UL)	01/03/91	8170.00		7060.00		6720.00	
WBC: N	50-70 (%)	01/03/91	62.50		63.50		49.50 <	
WBC: L	25-45 (%)	01/03/91	27.50		27.10		38.50	
WBC: E	1-3 (%)	01/03/91	1.70		0.80 <		1.10	
WBC: M	2-9 (%)	01/03/91	7.30		7.80		10.10 >	
WBC: B	0-1 (%)	01/03/91	1.00		0.70		0.80	
PLATELETS	200000-400000 (/UL)	01/03/91	207000		303000		244000	
NA+	135-145 (MEQ/L)	01/03/91	141.00		137.00		139.00	
K+	3.6-4.9 (MEQ/L)	01/03/91	4.40		4.70		3.60	
CL-	95-105 (MEQ/L)	01/03/91	100.00		96.00		98.00	
Ca++	95-105 (MG/L)	01/03/91	103.00		97.00		105.00	
PO4--	25-48 (MG/L)	01/03/91	34.00		29.00		36.00	
SGOT	10-41 (UI/L)	01/03/91	20.00		14.00		18.00	
SGPT	10-41 (UI/L)	01/03/91	15.00		13.00		12.00	
GAMMA GT	7-36 (UI/L)	01/03/91	11.00		16.00		12.00	
LDH	220-440 (UI/L)	01/03/91	373.00		270.00		312.00	
ALK. PHOSPH.	35-110 (UI/L)	01/03/91	89.00		78.00		87.00	
GLUCOSE	0.8-1.1 (G/L)	01/03/91	1.09		1.12 >		0.87	
UREA	0.2-0.5 (G/L)	01/03/91			0.44			
CREATININE	7-13 (MG/L)	01/03/91	7.10		6.50 <		7.80	
URIC ACID	23-70 (MG/L)	01/03/91	25.00		22.00 <		26.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/03/91	2.40		1.90		3.80	
TOT. PROTEINS	65-80 (G/L)	01/03/91	68.00		67.00		71.00	
ALBUMINE	37-52 (G/L)	01/03/91	44.90		42.30		38.00	
TOT. CHOLEST.	1.5-2.5 (G/L)	01/03/91	1.26 <		1.35 <		1.50	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/03/91	0.74		0.60		0.95	
GLOBULINS ALPHA 1	1-3 (G/L)	01/03/91	2.00		2.20		2.70	
GLOBULINS ALPHA 2	4-7 (G/L)	01/03/91	5.80		6.10		7.70 >	
GLOBULINS BETA	5-8 (G/L)	01/03/91	7.10		7.10		9.30 >	
GLOBULINS GAMMA	8-12 (G/L)	01/03/91	8.10		8.90		13.30 >	

1662

(±) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/4 Patient: 35 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/09/92		03/10/92		27/10/92	
			value	(±)	value	(±)	value	(±)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/03/91	13.20		13.20		12.50 <	
HT	39-52 (%)	01/03/91	39.70		37.70 <		36.30 <	
RBC	4.2-5.7 (10 ⁶ /UL)	01/03/91	3.83 <		3.80 <		3.65 <	
WBC	5000-9000 (/UL)	01/03/91	5490.00		6160.00		6480.00	
WBC: N	50-70 (%)	01/03/91	32.70 <<		39.80 <		62.10	
WBC: L	25-45 (%)	01/03/91	60.80 >>		52.90 >		30.50	
WBC: E	1-3 (%)	01/03/91	1.00		1.80		1.80	
WBC: M	2-9 (%)	01/03/91	4.60		4.60		5.10	
WBC: B	0-1 (%)	01/03/91	1.00		0.80		0.60	
PLATELETS	200000-400000 (/UL)	01/03/91	173000 <		166000 <		130000 <<	
NA+	135-145 (MEQ/L)	01/03/91	136.00		140.00		142.00	
K+	3.6-4.9 (MEQ/L)	01/03/91	4.80		4.80		4.50	
CL-	95-105 (MEQ/L)	01/03/91	95.00		99.00		102.00	
Ca++	95-105 (MG/L)	01/03/91	102.00		95.00		95.00	
PO4--	25-48 (MG/L)	01/03/91	36.00		37.00		40.00	
SGOT	10-41 (UI/L)	01/03/91	26.00		25.00		27.00	
SGPT	10-41 (UI/L)	01/03/91	19.00		17.00		11.00	
GAMMA GT	7-36 (UI/L)	01/03/91	19.00		12.00		18.00	
LDH	220-440 (UI/L)	01/03/91	261.00		299.00		461.00 >	
ALK. PHOSPH.	35-110 (UI/L)	01/03/91	79.00		131.00 >		89.00	
GLUCOSE	0.8-1.1 (G/L)	01/03/91	0.80		0.79 <		1.42 >	
UREA	0.2-0.5 (G/L)	01/03/91			0.16 <		0.19 <	
CREATININE	7-13 (MG/L)	01/03/91	9.40		9.90		9.60	
URIC ACID	23-70 (MG/L)	01/03/91	61.00		55.00		59.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/03/91	4.00		3.60		0.60	
TOT. PROTEINS	65-80 (G/L)	01/03/91	71.00		71.00		70.00	
ALBUMINE	57-65 (%)	01/03/91	68.70 >		66.50 >		65.90 >	
TOT. CHOLEST.	1.5-2.5 (G/L)	01/03/91	2.18		1.74		1.99	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/03/91	1.51		1.56		1.25	
GLOBULINS ALPHA 1	2-4 (%)	01/03/91	2.50		3.10		3.80	
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	9.40		8.90		10.90 >	
GLOBULINS BETA	8-12 (%)	01/03/91	8.70		7.80 <		8.60	
GLOBULINS GAMMA	12-19 (%)	01/03/91	10.70 <		13.70		10.80 <	
TSH	0.25-5 (MU/L)	01/03/91	2.89					
T4	8-22 (PMOL/L)	01/03/91	8.50					

1663

(±) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/4 Patient: 36 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/02/92		04/03/92		25/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/01/92	12.40	<	13.90		14.00	
HT	39-52 (X)	01/01/92	41.80		43.40		42.30	
RBC	4.2-5.7 (10 ⁶ /UL)	01/01/92	4.03	<	4.54		4.61	
WBC	5000-9000 (/UL)	01/01/92	2190.00	<<	3250.00	<<	3100.00	
WBC: N	50-70 (X)	01/01/92	53.80		72.90	>	75.10	
WBC: L	25-45 (X)	01/01/92	36.60		19.10	<	16.10	
WBC: E	1-3 (X)	01/01/92	1.50		1.20		0.50	
WBC: M	2-9 (X)	01/01/92	7.40		6.00		7.80	
WBC: B	0-1 (X)	01/01/92	0.80		0.80		0.50	
PLATELETS	200000-400000 (/UL)	01/01/92	96000.0	<<	146000	<	160000	
NA+	135-145 (MEQ/L)	01/01/92	137.00		135.00		133.00	
K+	3.6-4.9 (MEQ/L)	01/01/92	2.80	<<	3.00	<<	3.30	
CL-	95-105 (MEQ/L)	01/01/92	93.00	<	94.00	<	91.00	
Ca++	95-105 (MG/L)	01/01/92	95.00		105.00		100.00	
PO4--	25-48 (MG/L)	01/01/92	22.00	<	23.00	<	36.00	
SCOT	10-41 (UI/L)	01/01/92	138.00	>>	28.00		40.00	
SGPT	10-41 (UI/L)	01/01/92	124.00	>>	13.00		14.00	
GAMMA GT	7-36 (UI/L)	01/01/92	308.00	>>	104.00	>>	128.00	
LDR	220-440 (UI/L)	01/01/92	363.00		293.00		417.00	
ALK. PHOSPH.	35-110 (UI/L)	01/01/92	203.00	>	112.00	>	209.00	
GLUCOSE	0.8-1.1 (G/L)	01/01/92	2.62	>>	0.73	<	0.95	
UREA	0.2-0.5 (G/L)	01/01/92			0.11	<	0.13	
CREATININE	7-13 (MG/L)	01/01/92	7.90		7.00		6.80	
URIC ACID	23-70 (MG/L)	01/01/92	30.00		40.00		45.00	
TOT BILIRUBIN	0-10 (MG/L)	01/01/92	10.60	>	4.70		6.90	
TOT. PROTEINS	65-80 (G/L)	01/01/92	70.00		74.00		78.00	
ALBUMINE	37-52 (G/L)	01/01/92	38.90		41.90		44.10	
TOT. CHOLEST.	1.5-2.5 (G/L)	01/01/92	1.71		1.82		1.62	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/01/92	1.86	>	0.78		0.89	
GLOBULINS ALPHA 1	2-4 (X)	01/01/92	4.60	>	4.80	>	5.00	
GLOBULINS ALPHA 2	6-10 (X)	01/01/92	9.10		11.50	>	12.10	
GLOBULINS BETA	8-12 (X)	01/01/92	10.10		12.00		11.00	
GLOBULINS GAMMA	12-19 (X)	01/01/92	20.90	>	15.00		15.60	

1664

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/5 Patient: 73 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/02/92		02/03/92		24/03/92	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	8-11 (MMOL/L)	01/02/92	8.80		8.40			
	8-13 (G/DL)	20/03/92				15.10	>	
HT	38-52 (%)	01/02/92	42.00		39.00			
	40-48 (%)	20/03/92				43.70		
RBC	4.2-5.7 (10 ⁶ /UL)	01/02/92	4.70		4.42			
	4.5-5.5 (10 ⁶ /UL)	20/03/92				4.89		
WBC	4-10 (10 ³ /UL)	01/02/92	5.48		6.23			
	5-10 (10 ³ /UL)	20/03/92				5.73		
WBC: N	45-74 (%)	01/02/92	65.50		58.80			
	45-70 (%)	20/03/92				65.00		
WBC: L	16-45 (%)	01/02/92	25.40		32.70			
	20-40 (%)	20/03/92				27.50		
WBC: E	0-7 (%)	01/02/92	3.30		2.20			
	1-2 (%)	20/03/92				2.10	>	
WBC: M	4-10 (%)	01/02/92	4.70		5.40			
	2-8 (%)	20/03/92				4.60		
WBC: B	0-2 (%)	01/02/92	0.70		0.60			
	0-1 (%)	20/03/92				0.80		
PLATELETS	150-400 (10 ³ /UL)	01/02/92	200.00		263.00			
NA+	135-145 (MEQ/L)	01/02/92	143.00		143.00			
	138-148 (MEQ/L)	20/03/92				141.00		
K+	3.5-5 (MEQ/L)	01/02/92	4.60		4.20			
	3.8-5.3 (MEQ/L)	20/03/92				4.60		
CL-	95-105 (MEQ/L)	01/02/92	107.00	>	105.00		102.00	
Ca++	2.12-2.75 (MMOL/L)	01/02/92	2.29		2.23			
	85-105 (MG/L)	20/03/92				90.00		
PO4--	0.8-1.45 (MMOL/L)	01/02/92	1.17		0.86			
	30-45 (MG/L)	20/03/92				30.00		
SGOT	6-53 (UI/L)	01/02/92	13.00		40.00			
	5-25 (UI/L)	20/03/92				23.00		
SGPT	7-40 (UI/L)	01/02/92	14.00		88.00	>>		
	5-30 (UI/L)	20/03/92				73.00	>>	
GAMMA GT	8-38 (UI/L)	01/02/92	20.00		34.00			
	8-33 (UI/L)	20/03/92				37.00	>	
LDH	160-280 (UI/L)	01/02/92	132.00	<	159.00	<		
	150-320 (UI/L)	20/03/92				164.00		
ALK. PHOSPH.	30-85 (UI/L)	01/02/92	73.00		109.00	>		
	80-220 (UI/L)	20/03/92				148.00		
GLUCOSE	3.9-5.55 (MMOL/L)	01/02/92	4.66		4.83			
	0.7-1.1 (G/L)	20/03/92				0.98		
UREA	2.65-6.65 (MMOL/L)	01/02/92	6.59		6.02			
	0.18-0.5 (G/L)	20/03/92				0.37		
CREATININE	9-90 (UMOL/L)	01/02/92	88.00		97.00	>		
	5-12 (MG/L)	20/03/92				8.00		
URIC ACID	150-475 (UMOL/L)	01/02/92	277.00		293.00			
	34-70 (MG/L)	20/03/92				48.00		
TOT BILIRUBIN	2-17 (UMOL/L)	01/02/92	9.00		9.00			
TOT. PROTEINS	60-75 (G/L)	01/02/92	60.00		60.00			
	68-83 (G/L)	20/03/92				73.00		
ALBUMINE	500-725 (UMOL/L)	01/02/92	639.00		598.00			
	40-55 (G/L)	20/03/92				48.35		
TOT. CHOLEST.	1.3-2.4 (G/L)	01/02/92	3.60	>>			2.42	
TRIGLYCERIDES	0.85-1.95 (MMOL/L)	01/02/92	0.93		1.35			
	0.5-1.6 (G/L)	20/03/92				0.79		
GLOBULINS ALPHA 1	2-4 (%)	01/02/92	3.00		3.00			
	2-5 (%)	20/03/92				2.90		
GLOBULINS ALPHA 2	6-10 (%)	01/02/92	6.00		7.00		6.30	
GLOBULINS BETA	8-12 (%)	01/02/92	11.00		11.00			
	8-14 (%)	20/03/92				11.70		
GLOBULINS GAMMA	12-19 (%)	01/02/92	12.00		12.00		<	

1665

(ø) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/5 Patient: 74 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/06/92		11/07/92		01/08/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	8-11 (MMOL/L) ()	10/06/92 10/07/92	9.10					
HT	8-13 (G/DL) ()	30/07/92 10/07/92					14.30	>
	0.38-0.52 (L/L) 40-48 (X)	10/06/92 30/07/92	0.46				43.00	
RBC	()	10/07/92						
	4.2-5.7 (10 ⁶ /MM3) 4.5-5.6 (10 ⁶ /MM3)	10/06/92 30/07/92	5.16				5.03	
HBC	()	10/07/92						
	4-10 (10 ³ /MM3) 5-10 (10 ³ /MM3)	10/06/92 30/07/92	10.56	>			9.70	
HBC: N	()	10/07/92						
	45-74 (X) 45-70 (X)	10/06/92 30/07/92	69.70				79.00	>
HBC: L	()	10/07/92						
	16-45 (X) 20-40 (X)	10/06/92 30/07/92	21.60				27.00	
HBC: E	()	10/07/92						
	0-7 (X) 1-2 (X)	10/06/92 30/07/92	2.00				1.00	
HBC: M	()	10/07/92						
	4-10 (X) 2-8 (X)	10/06/92 30/07/92	4.80				7.00	
HBC: B	()	10/07/92						
	0-2 (X) 0-1 (X)	10/06/92 30/07/92	1.50				0.00	
PLATELETS	150-400 (10 ³ /MM3)	10/06/92	299.00				245.00	
NA+	135-145 (MMOL/L) 138-145 (MMOL/L)	10/06/92 10/07/92	144.00					
	138-148 (MMOL/L)	30/07/92			140.00		142.00	
K+	3.5-5 (MMOL/L) 3.8-5.3 (MMOL/L)	10/06/92 30/07/92	4.20		4.30		4.20	
CL-	95-105 (MMOL/L) 98-105 (MMOL/L)	10/06/92 10/07/92	110.00	>			100.00	
Ca++	2.12-2.75 (MMOL/L) 2-2.63 (MMOL/L)	10/06/92 10/07/92	2.33		106.00	>	2.20	
PO4--	0.8-1.45 (MMOL/L) 0.86-1.44 (MMOL/L)	10/06/92 10/07/92	1.16			2.35		
	30-45 (MG/L)	30/07/92				1.24	36.00	
SGOT	6-53 (UI/L) 5-25 (UI/L)	10/06/92 10/07/92	18.00			11.00	15.00	
SGPT	7-40 (UI/L) 5-29 (UI/L)	10/06/92 10/07/92	14.00			17.00		
	5-30 (UI/L)	30/07/92					10.00	
GAMMA GT	8-38 (UI/L) 8-33 (UI/L)	10/06/92 30/07/92	19.00		4.00	<	18.00	
LDH	160-280 (UI/L) 140-330 (UI/L)	10/06/92 10/07/92	181.00					
	150-320 (UI/L)	30/07/92					194.00	
ALK. PROSPH.	()	10/07/92						
	30-85 (UI/L) 80-220 (UI/L)	10/06/92 30/07/92	81.00				47.00	<
GLUCOSE	3.9-5.55 (MMOL/L) 3.85-5.56 (MMOL/L)	10/06/92 10/07/92	5.44			5.06		
	0.7-1.1 (G/L)	30/07/92					0.85	
BUN	()	10/06/92						
UREA	2.65-6.65 (MMOL/L) 1.65-6.64 (MMOL/L)	10/06/92 10/07/92	7.37	>		5.64		
	0.18-0.5 (G/L)	30/07/92					0.41	
CREATININE	9-90 (UMOL/L) 44-98 (UMOL/L)	10/06/92 10/07/92	111.00	>		101.78	>	

1666

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(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/5 Patient: 74 Treatment: Roboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/06/92		11/07/92		01/08/92	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
CREATININE	5-12 (MG/L)	30/07/92						
URIC ACID	150-475 (UMOL/L)	10/06/92	284.00		226.00		11.00	
	178-416 (UMOL/L)	10/07/92						
	34-70 (MG/L)	30/07/92					33.00	<
TOT BILIRUBIN	2-17 (UMOL/L)	10/06/92	12.00					
	0-10 (MG/L)	10/07/92			7.06		10.00	
	()	10/06/92						
DIR BILIRUBIN	60-75 (G/L)	10/06/92						
TOT. PROTEINS	60-88 (G/L)	10/07/92	61.00		59.00	<		
	68-83 (G/L)	30/07/92					66.00	
	()	10/07/92						
ALBUMINE	500-725 (UMOL/L)	10/06/92	599.00					
	52-62 (X)	30/07/92					53.70	
TOT. CHOLEST.	3.9-6.3 (MMOL/L)	10/06/92	6.02					
	4.64-6.45 (MMOL/L)	10/07/92			5.16			
	1.3-2.4 (G/L)	30/07/92					2.34	
TRIGLYCERIDES	0.85-1.96 (MMOL/L)	10/06/92	1.55					
	0.85-1.72 (MMOL/L)	10/07/92			1.05			
	0.5-1.6 (G/L)	30/07/92						
	()	10/07/92						
GLOBULINS ALPHA 1	2-4 (X)	10/06/92	3.50					
	2-5 (X)	30/07/92					2.10	
	()	10/07/92						
GLOBULINS ALPHA 2	6-10 (X)	10/06/92	9.50				13.50	>>
	()	10/07/92						
GLOBULINS BETA	8-12 (X)	10/06/92	11.40				12.50	
	8-14 (X)	30/07/92						
	()	10/07/92						
GLOBULINS GAMMA	12-19 (X)	10/06/92	8.80	<			18.20	
	()	10/07/92						
TSH	0.2-5 (MUI/L)	10/06/92						
	()	10/07/92						
T4	11-24 (PMOL/L)	10/06/92						

1667

(ϕ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/5 Patient: 75 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/09/92		01/10/92		22/10/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	8-11 (MMOL/L)	01/09/92	10.20		10.70			
HT	0.38-0.52 (L/L)	01/09/92	0.50		0.52			
RBC	4.2-5.7 (10 ¹² /L)	01/09/92	5.53		5.63			
WBC	4-10 (10 ⁹ /L)	01/09/92	8.91		9.60			
WBC: N	45-74 (%)	01/09/92	61.30		62.70			
WBC: L	16-45 (%)	01/09/92	30.50		28.10			
WBC: E	0-7 (%)	01/09/92	1.60		1.70			
WBC: M	4-10 (%)	01/09/92	0.50	<	5.80			
WBC: B	0-2 (%)	01/09/92	0.80		1.00			
PLATELETS	150-400 (10 ⁹ /L)	01/09/92	235.00		306.00			
NA+	135-145 (MMOL/L)	01/09/92	140.00		142.00			
	135-148 (MMOL/L)	20/10/92				136.00		
K+	3.5-5 (MMOL/L)	01/09/92	4.20		4.30			
	3.8-4.8 (MMOL/L)	20/10/92				4.70		
CL-	95-105 (MMOL/L)	01/09/92	106.00	>	104.00			
	96-106 (MMOL/L)	20/10/92				97.00		
Ca++	2.12-2.75 (MMOL/L)	01/09/92	2.26		2.35			
	2.02-2.71 (MMOL/L)	20/10/92				2.10		
PO4--	0.8-1.45 (MMOL/L)	01/09/92	0.84		0.84			
	0.8-1.6 (MMOL/L)	20/10/92				1.30		
SGOT	6-53 (UI/L)	01/09/92	17.00		20.00		17.00	
SGPT	7-40 (UI/L)	01/09/92	14.00		16.00			
	7-56 (UI/L)	20/10/92				12.00		
GAMMA GT	8-38 (UI/L)	01/09/92	11.00		16.00			
	7-78 (UI/L)	20/10/92				33.00		
LDH	160-280 (UI/L)	01/09/92			218.00			
	313-618 (U/L)	20/10/92				590.00		
ALK. PHOSPH.	30-85 (UI/L)	01/09/92	51.00		71.00			
	38-126 (UI/L)	20/10/92				72.00		
GLUCOSE	3.9-5.55 (MMOL/L)	01/09/92	4.77		4.50			
	3.89-6.11 (MMOL/L)	20/10/92				4.73		
UREA	2.65-6.65 (MMOL/L)	01/09/92	4.81		5.41			
	1.66-8.33 (MMOL/L)	20/10/92				5.34		
CREATININE	9-90 (UMOL/L)	01/09/92	89.00		93.00	>		
	20-132 (UMOL/L)	20/10/92				88.50		
URIC ACID	150-475 (UMOL/L)	01/09/92	325.00		362.00			
	208-357 (UMOL/L)	20/10/92				309.00		
TOT BILIRUBIN	2-17 (UMOL/L)	01/09/92	15.00		10.00		15.00	
TOT. PROTEINS	60-75 (G/L)	01/09/92	63.00		68.00			
	65-75 (G/L)	20/10/92				75.00		
ALBUMINE	500-725 (UMOL/L)	01/09/92	580.00		618.00			
	34-52 (G/L)	20/10/92				45.08		
TOT. CHOLEST.	3.9-6.3 (MMOL/L)	01/09/92	5.82		8.08	>		
	3.87-6.19 (MMOL/L)	20/10/92				7.04	>	
TRIGLYCERIDES	0.85-1.96 (MMOL/L)	01/09/92	2.49	>	3.43	>>		
	0.57-1.82 (MMOL/L)	20/10/92				3.42	>>	
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	3.30					
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	8.00					
	10-14 (%)	20/10/92				11.10		
GLOBULINS BETA	8-12 (%)	01/09/92	11.80					
	6-13 (%)	20/10/92				12.80		
GLOBULINS GAMMA	12-19 (%)	01/09/92	13.10					
	10-19 (%)	20/10/92				12.20		
TSH	0.2-5 (mUI/mL)	01/09/92	1.49					
T4	11-24 (PMOL/L)	01/09/92	17.70					

1668

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/5 Patient: 76 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/09/92		02/10/92		28/10/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	7.4-9.9 (MMOL/L)	01/04/92	9.40		8.60		8.50	
HT	0.32-0.47 (L/L)	01/04/92	0.44		0.43		0.42	
RBC	4-5.5 (10 ¹² /L)	01/04/92	4.56		4.43		4.26	
WBC	4-10 (10 ⁹ /L)	01/04/92	10.00		6.77		8.61	
WBC: N	45-74 (%)	01/04/92	61.70		54.50		60.70	
WBC: L	16-45 (%)	01/04/92	30.80		36.30		29.10	
WBC: E	0-7 (%)	01/04/92	2.40		3.20		3.90	
WBC: M	4-10 (%)	01/04/92	4.50		4.60		5.10	
WBC: B	0-2 (%)	01/04/92	0.50		0.80		0.70	
PLATELETS	150-400 (10 ⁹ /L)	01/04/92	348.00				341.00	
NA+	135-145 (MMOL/L)	01/04/92	140.00		142.00		140.00	
K+	3.5-5 (MMOL/L)	01/04/92	4.10		4.60		4.50	
CL-	95-105 (MMOL/L)	01/04/92	105.00		104.00		103.00	
Ca++	2.12-2.75 (MMOL/L)	01/04/92	2.34		2.48		2.39	
PO4--	0.8-1.45 (MMOL/L)	01/04/92	1.30		1.39		1.14	
SGOT	6-53 (UI/L)	01/04/92	13.00		15.00		20.00	
SGPT	7-40 (UI/L)	01/04/92	14.00		12.00		41.00 >	
GAMMA GT	5-20 (UI/L)	01/04/92	30.00 >		22.00 >			
LDH	160-280 (UI/L)	01/04/92	181.00		161.00			
ALK. PHOSPH.	30-85 (UI/L)	01/04/92	43.00		31.00		35.00	
GLUCOSE	3.9-5.55 (MMOL/L)	01/04/92	5.11		5.00		4.83	
UREA	2.65-6.65 (MMOL/L)	01/04/92	5.62		4.66		3.67	
CREATININE	9-90 (UMOL/L)	01/04/92	72.00		86.00		80.00	
URIC ACID	150-475 (UMOL/L)	01/04/92	139.00 <		198.00		186.00	
TOT. BILIRUBIN	2-17 (UMOL/L)	01/04/92	2.93		9.00		5.00	
TOT. PROTEINS	60-75 (G/L)	01/04/92	65.00		67.00			
ALBUMINE	500-725 (UMOL/L)	01/04/92	609.00		623.00			
TOT. CHOLEST.	3.9-6.3 (MMOL/L)	01/04/92					5.69	
TRIGLYCERIDES	0.85-1.96 (MMOL/L)	01/04/92					3.12 >>	
TSH	0.2-5 (MUI/L)	01/04/92	1.25					
T4	11-24 (PMOL/L)	01/04/92	14.10					

1669

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/5 Patient: 77 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/09/92		13/10/92		30/10/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	8-11 (MMOL/L)	01/04/92	10.10		9.30		9.50	
HT	0.38-0.52 (L/L)	01/04/92	0.48		0.46		0.46	
RBC	4.2-5.7 (10 ¹² /L)	01/04/92	5.14		4.88		4.87	
HBC	4-10 (10 ⁹ /L)	01/04/92	6.78		7.69		8.12	
HBC: N	45-74 (%)	01/04/92	57.00		56.00		72.20	
HBC: L	16-45 (%)	01/04/92	33.50		33.10		18.50	
HBC: E	0-7 (%)	01/04/92	2.00		2.90		0.90	
HBC: M	4-10 (%)	01/04/92	6.70		7.00		7.60	
HBC: B	0-2 (%)	01/04/92	0.40		0.40		0.60	
PLATELETS	150-400 (10 ⁹ /L)	01/04/92	257.00		298.00		327.00	
NA+	135-145 (MMOL/L)	01/04/92	140.00		143.00		142.00	
K+	3.5-5 (MMOL/L)	01/04/92	4.40		4.50		4.50	
CL-	95-105 (MMOL/L)	01/04/92	101.00		106.00 >		108.00 >	
Ca++	2.12-2.75 (MMOL/L)	01/04/92	2.44		2.36		2.42	
PO4--	0.8-1.45 (MMOL/L)	01/04/92	1.18		1.07		1.01	
SGOT	6-53 (UI/L)	01/04/92	21.00		28.00		19.00	
SGPT	7-40 (UI/L)	01/04/92	43.00 >		27.00		16.00	
GAMMA GT	8-38 (UI/L)	01/04/92	50.00 >		21.00		16.00	
LDH	160-280 (UI/L)	01/04/92	118.00 <				186.00	
ALK. PHOSPH.	30-85 (UI/L)	01/04/92	105.00 >		90.00 >		89.00 >	
GLUCOSE	3.9-5.55 (MMOL/L)	01/04/92	4.16		4.22		5.33	
UREA	2.65-6.65 (MMOL/L)	01/04/92	5.23		5.62		7.16 >	
CREATININE	9-90 (UMOL/L)	01/04/92	112.00 >		95.00 >		104.00 >	
URIC ACID	150-475 (UMOL/L)	01/04/92	306.00		423.00		467.00	
TOT. BILIRUBIN	2-17 (UMOL/L)	01/04/92	9.00		14.00		2.93	
TOT. PROTEINS	60-75 (G/L)	01/04/92	67.00		67.00		69.00	
ALBUMINE	500-725 (UMOL/L)	01/04/92	636.00		624.00		619.00	
TOT. CHOLEST.	3.9-6.3 (MMOL/L)	01/04/92	5.78		5.20		4.49	
TRIGLYCERIDES	0.85-1.96 (MMOL/L)	01/04/92	1.44		0.62 <		0.51 <	
GLOBULINS ALPHA 1	2-4 (%)	01/04/92			2.80		4.20 >	
GLOBULINS ALPHA 2	6-10 (%)	01/04/92			7.40		7.30	
GLOBULINS BETA	8-12 (%)	01/04/92			11.40		11.50	
GLOBULINS GAMMA	12-19 (%)	01/04/92			12.70		14.00	
TSH	0.2-5 (MUI/L)	01/04/92	4.63					
T4	11-24 (PMOL/L)	01/04/92	13.30					

1670

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Laboratory test	Range value	Range date	Screen		Day 21	
			value (±)	value (±)	value (±)	value (±)
Hb	7.4-9.5 (MMOL/L)	01/04/92	6.70 <	7.30 <		
Ht	0.32-0.47 (L/L)	01/04/92	0.34 <	0.34 <		
RBC	4.3-5.3 (10 ¹² /L)	01/04/92	3.69 <	3.70 <		
HbC	4-10 (10 ⁹ /L)	01/04/92	6.57	9.10		
HbC: N	43-74 (Z)	01/04/92	65.50			
HbC: L	16-45 (Z)	01/04/92	27.10			
HbC: E	0-7 (Z)	01/04/92	1.90			
HbC: B	4-10 (Z)	01/04/92	4.20			
PLATELETS	0-2 (Z)	01/04/92	0.60			
NA+	150-400 (10 ⁹ /L)	01/04/92	368.00	348.00		
CL-	135-145 (MMOL/L)	01/04/92	139.00	135.00		
K+	3.5-5 (MMOL/L)	01/04/92	4.00	3.70		
Ca++	95-105 (MMOL/L)	01/04/92	103.00	104.00		
PO4--	2.12-2.75 (MMOL/L)	01/04/92	1.25	2.16		
SGPT	0.8-1.45 (MMOL/L)	01/04/92	13.00			
ALK. PHOSPH.	7-40 (UI/L)	01/04/92	10.00			
GLUCOSE	30-85 (UI/L)	01/04/92	65.00			
UREA	2.65-6.65 (MMOL/L)	01/04/92	4.72	5.30		
CREATININE	9-90 (UMOL/L)	01/04/92	57.00	4.30		
URIC ACID	150-475 (UMOL/L)	01/04/92	202.00	58.00		
TOT. BILIRUBIN	2-17 (UMOL/L)	01/04/92	5.00	73.00		
TOT. PROTEINS	60-75 (G/L)	01/04/92	67.00			
ALBUMINE	500-725 (UMOL/L)	01/04/92	549.00			
TRIGLYCERIDS	0.85-1.96 (MMOL/L)	01/04/92	6.34 >			
GLOBULINS ALPHA 1	2-6 (Z)	01/04/92	1.03			
GLOBULINS ALPHA 2	6-10 (Z)	01/04/92	7.00			
GLOBULINS BETA	8-12 (Z)	01/04/92	13.00 >			
GLOBULINS GAMMA	12-19 (Z)	01/04/92	18.00			
TSH	0.2-5 (MUI/L)	01/04/92	1.39			
T4	11-24 (PMOL/L)	01/04/92	16.80			

1671

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/6 Patient: 55 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 42
			15/06/92	20/07/92
			value (☐)	value (☐)
Laboratory test	Range value	Range date		
HB	12-16 (G/L)	05/04/92	12.40	13.90
HT	36-47 (X)	05/04/92	40.00	41.00
RBC	4-5.4 (10 ⁶ /UL)	05/04/92	4.01	4.21
WBC	4000-10000 (/UL)	05/04/92	2100.00	<< 2700.00 <<
WBC: N	50-70 (%)	05/04/92	59.00	54.00
WBC: L	20-40 (%)	05/04/92	30.00	35.00
WBC: E	1-5 (%)	05/04/92	1.00	4.00
WBC: M	3-10 (%)	05/04/92	10.00	7.00
WBC: B	0-1 (%)	05/04/92	0.00	0.00
PLATELETS	150-350 (10 ³ /UL)	05/04/92	70.00	<< 65.00 <<
NA+	135-145 (MEQ/L)	05/04/92	140.00	145.00
K+	3.5-5 (MEQ/L)	05/04/92	3.40	< 3.80
CL-	96-110 (MEQ/L)	05/04/92	108.00	109.00
SGOT	5-30 (UI/L)	05/04/92	62.00	>> 16.00
SGPT	5-40 (UI/L)	05/04/92	31.00	7.00
GAMMA GT	7-29 (UI/L)	05/04/92	392.00	>> 92.00 >>
ALK. PHOSPH.	50-90 (UI/L)	05/04/92	113.00	> 88.00
GLUCOSE	0.7-1.05 (G/L)	05/04/92	0.84	0.84
UREA	0.2-0.4 (G/L)	05/04/92	0.28	0.24
CREATININE	6-12 (MG/L)	05/04/92	8.00	7.00
URIC ACID	25-60 (MG/L)	05/04/92	43.00	35.00
TOT. CHOLEST.	1.5-2.3 (G/L)	05/04/92	1.98	1.89
TRIGLYCERIDES	0.5-1.4 (G/L)	05/04/92	0.42	< 0.60
TSH	0.4-4 (UU/ML)	05/04/92	1.60	
T4	7-18 (PG/ML)	05/04/92	7.00	

1672

(☐) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/6 Patient: 56 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 42
			15/06/92	24/07/92
			value (c)	value (c)
Laboratory test	Range value	Range date		
HB	12-16 (G/L)	05/04/92	12.90	14.20
HT	36-47 (%)	05/04/92	40.00	44.00
RBC	4-5.4 (10 ⁶ /UL)	05/04/92	4.19	4.76
WBC	4000-10000 (/UL)	05/04/92	4700.00	5300.00
WBC: N	50-70 (%)	05/04/92	49.00	< 52.00
WBC: L	20-40 (%)	05/04/92	43.00	> 39.00
WBC: E	1-5 (%)	05/04/92	3.00	3.00
WBC: M	3-10 (%)	05/04/92	5.00	6.00
WBC: B	0-1 (%)	05/04/92	0.00	0.00
PLATELETS	150-350 (10 ³ /UL)	05/04/92	180.00	220.00
NA+	135-145 (MEQ/L)	05/04/92	142.00	142.00
K+	3.5-5 (MEQ/L)	05/04/92	3.60	3.60
CL-	96-110 (MEQ/L)	05/04/92	107.00	105.00
SGOT	5-30 (UI/L)	05/04/92	8.00	9.00
SGPT	5-40 (UI/L)	05/04/92	7.00	8.00
GAMMA GT	7-29 (UI/L)	05/04/92	9.00	13.00
ALK. PHOSPH.	50-90 (UI/L)	05/04/92	70.00	74.00
GLUCOSE	0.7-1.05 (G/L)	05/04/92	0.80	0.87
UREA	0.2-0.4 (G/L)	05/04/92	0.30	0.31
CREATININE	6-12 (MG/L)	05/04/92	9.00	8.00
URIC ACID	25-60 (MG/L)	05/04/92	48.00	41.00
TOT. CHOLEST.	1.5-2.3 (G/L)	05/04/92	1.80	2.02
TRIGLYCERIDES	0.5-1.4 (G/L)	05/04/92	1.38	1.40
TSH	0.4-4 (UU/ML)	05/04/92	2.60	
T4	7-18 (PG/ML)	05/04/92	9.00	

1673

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 2/6 Patient: 57 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 42
			30/04/92	15/06/92
			value (⊕)	value (⊕)
Laboratory test	Range value	Range date		
HB	12-16 (G/L)	05/04/92	13.00	13.60
HT	36-47 (%)	05/04/92	39.00	42.00
RBC	4-5.4 (10 ⁶ /UL)	05/04/92	4.44	4.69
WBC	4000-10000 (/UL)	05/04/92	6500.00	6500.00
WBC: N	50-70 (%)	05/04/92	68.00	75.00 >
WBC: L	20-40 (%)	05/04/92	26.00	21.00
WBC: E	1-5 (%)	05/04/92	2.00	2.00
WBC: M	3-10 (%)	05/04/92	4.00	2.00 <
WBC: B	0-1 (%)	05/04/92	0.00	0.00
PLATELETS	150-350 (10 ³ /UL)	05/04/92	290.00	230.00
NA+	135-145 (MEQ/L)	05/04/92	141.00	140.00
K+	3.5-5 (MEQ/L)	05/04/92	4.40	3.80
CL-	96-110 (MEQ/L)	05/04/92	106.00	105.00
SGOT	5-30 (UI/L)	05/04/92	12.00	16.00
SGPT	5-40 (UI/L)	05/04/92	14.00	17.00
GAMMA GT	7-29 (UI/L)	05/04/92	31.00 >	44.00 >
ALK. PHOSPH.	50-90 (UI/L)	05/04/92	85.00	93.00 >
GLUCOSE	0.7-1.05 (G/L)	05/04/92	1.22 >	0.88
UREA	0.2-0.4 (G/L)	05/04/92	0.35	0.31
CREATININE	6-12 (MG/L)	05/04/92	9.00	10.00
URIC ACID	25-60 (MG/L)	05/04/92	46.00	46.00
TOT. CHOLEST.	1.5-2.3 (G/L)	05/04/92	2.44 >	2.50 >
TRIGLYCERIDES	0.5-1.4 (G/L)	05/04/92	1.59 >	1.59 >
TSH	0.4-4 (UU/ML)	05/04/92		2.00
T4	7-18 (PG/ML)	05/04/92		7.50

167 1/4

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/6 Patient: 58 Treatment: Placebo Sex: Female

			Visit number / Laboratory date			
			Screen		Day 42	
			18/05/92		24/06/92	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	12-16 (G/L)	05/04/92	12.50		11.80	<
HT	36-47 (X)	05/04/92	37.00		36.00	
RBC	4-5.4 (10 ⁶ /UL)	05/04/92	3.90	<	3.80	<
WBC	4000-10000 (/UL)	05/04/92	6500.00		5700.00	
WBC: N	50-70 (X)	05/04/92	65.00		67.00	
WBC: L	20-40 (X)	05/04/92	27.00		24.00	
WBC: E	1-5 (X)	05/04/92	3.00		3.00	
WBC: M	3-10 (X)	05/04/92	5.00		6.00	
WBC: B	0-1 (X)	05/04/92	0.00		0.00	
PLATELETS	150-350 (10 ³ /UL)	05/04/92	260.00		265.00	
NA+	135-145 (MEQ/L)	05/04/92	139.00		138.00	
K+	3.5-5 (MEQ/L)	05/04/92	3.70		3.60	
CL-	96-110 (MEQ/L)	05/04/92	109.00		109.00	
SGOT	5-30 (UI/L)	05/04/92	10.00		7.00	
SGPT	5-40 (UI/L)	05/04/92	9.00		8.00	
GAMMA GT	7-29 (UI/L)	05/04/92	17.00		24.00	
ALK. PHOSPH.	50-90 (UI/L)	05/04/92	54.00		49.00	<
GLUCOSE	0.7-1.05 (G/L)	05/04/92	0.95		0.99	
UREA	0.2-0.4 (G/L)	05/04/92	0.32		0.28	
CREATININE	6-12 (MG/L)	05/04/92	10.00		9.00	
URIC ACID	25-60 (MG/L)	05/04/92	42.00		40.00	
TOT. CHOLEST.	1.5-2.3 (G/L)	05/04/92	2.68	>	2.63	>
TRIGLYCERIDES	0.5-1.4 (G/L)	05/04/92	2.00	>>	1.28	
TSH	0.4-4 (IU/ML)	05/04/92			3.90	
T4	7-18 (PG/ML)	05/04/92			6.50	<

1675

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/6 Patient: 59 Treatment: Placebo Sex: Male

			Visit number / Laboratory date	
			Screen	Day 28
			29/05/92	26/06/92
			value (†)	value (‡)
Laboratory test	Range value	Range date		
HB	13-17 (G/L)	05/04/92	15.80	15.50
HT	40-54 (X)	05/04/92	46.00	47.00
RBC	4.2-5.7 (10 ⁶ /UL)	05/04/92	5.04	4.98
WBC	4000-10000 (/UL)	05/04/92	6900.00	6100.00
WBC: N	50-70 (X)	05/04/92	63.00	62.00
WBC: L	20-40 (X)	05/04/92	26.00	25.00
WBC: E	1-5 (X)	05/04/92	4.00	0.00 <
WBC: M	3-10 (X)	05/04/92	7.00	9.00
WBC: B	0-1 (X)	05/04/92	0.00	0.00
PLATELETS	150-350 (10 ³ /UL)	05/04/92	240.00	305.00
NA+	135-145 (MEQ/L)	05/04/92	140.00	136.00
K+	3.5-5 (MEQ/L)	05/04/92	3.70	4.00
CL-	96-110 (MEQ/L)	05/04/92	104.00	103.00
SGOT	5-30 (UI/L)	05/04/92	10.00	13.00
SGPT	5-40 (UI/L)	05/04/92	15.00	29.00
GAMMA GT	8-33 (UI/L)	05/04/92	17.00	33.00
ALK. PHOSPH.	50-90 (UI/L)	05/04/92	59.00	58.00
GLUCOSE	0.7-1.05 (G/L)	05/04/92	0.85	0.92
UREA	0.2-0.4 (G/L)	05/04/92	0.26	0.34
CREATININE	6-12 (MG/L)	05/04/92	11.00	11.00
URIC ACID	25-60 (MG/L)	05/04/92	61.00 >	54.00
TOT. CHOLEST.	1.5-2.3 (G/L)	05/04/92	2.55 >	2.29
TRIGLYCERIDES	0.5-1.4 (G/L)	05/04/92	1.21	0.69
TSH	0.4-4 (IU/ML)	05/04/92		1.90
T4	7-18 (PG/ML)	05/04/92		6.00 <<

1676

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 2/6 Patient: 60 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 42	
			06/04/92		23/06/92	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	12-16 (G/L)	05/04/92	15.00		13.20	
HT	36-47 (Z)	05/04/92	45.00		39.00	
RBC	4-5.4 (10 ⁶ /UL)	05/04/92	5.07		4.51	
WBC	4000-10000 (/UL)	05/04/92	7500.00		6800.00	
WBC: N	50-70 (%)	05/04/92	34.00	<<	41.00 <	
WBC: L	20-40 (%)	05/04/92	55.00	>>	42.00 >	
WBC: E	1-5 (%)	05/04/92	4.00		2.00	
WBC: M	3-10 (%)	05/04/92	7.00		15.00 >>	
WBC: B	0-1 (%)	05/04/92	0.00		0.00	
PLATELETS	150-350 (10 ³ /UL)	05/04/92	230.00		240.00	
NA+	135-145 (MEQ/L)	05/04/92	143.00		139.00	
K+	3.5-5 (MEQ/L)	05/04/92	3.80		4.00	
CL-	96-110 (MEQ/L)	05/04/92	104.00		102.00	
SGOT	5-30 (UI/L)	05/04/92	22.00		17.00	
SGPT	5-40 (UI/L)	05/04/92	28.00		24.00	
GAMMA GT	7-29 (UI/L)	05/04/92	27.00		41.00 >	
ALK. PHOSPH.	50-90 (UI/L)	05/04/92	57.00		71.00	
GLUCOSE	0.7-1.05 (G/L)	05/04/92	0.95		0.86	
UREA	0.2-0.4 (G/L)	05/04/92	0.26		0.33	
CREATININE	6-12 (MG/L)	05/04/92	10.00		9.00	
URIC ACID	25-60 (MG/L)	05/04/92	31.00		27.00	
TOT. CHOLEST.	1.5-2.3 (G/L)	05/04/92	1.96		1.93	
TRIGLYCERIDES	0.5-1.4 (G/L)	05/04/92	0.88		1.10	
TSH	0.4-4 (UU/ML)	05/04/92			1.90	
T4	7-18 (PG/ML)	05/04/92			4.50 <<	

1677

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 61 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 21
			04/03/91	03/04/91
			value (⊕)	value (⊕)
Laboratory test	Range value	Range date		
HB	12.5-17.5 (G/DL)	01/02/91	14.40	14.60
HT	40-55 (X)	01/02/91	42.80	43.20
RBC	4.5-5.8 (10 ⁶ /UL)	01/02/91	5.06	5.13
WBC	4500-9000 (/UL)	01/02/91	5300.00	5900.00
WBC: N	2700-6300 (/UL)	01/02/91	2756.00	3009.00
WBC: L	900-2700 (/UL)	01/02/91	2279.00	2301.00
WBC: E	45-360 (/UL)	01/02/91	212.00	354.00
WBC: M	90-540 (/UL)	01/02/91	53.00	236.00
WBC: B	0-90 (/UL)	01/02/91	0.00	0.00
PLATELETS	150-400 (10 ³ /UL)	01/02/91	219.00	241.00
NA+	138-148 (MEQ/L)	01/02/91	141.40	139.00
K+	3.8-5.6 (MEQ/L)	01/02/91	4.74	3.99
CL-	95-108 (MEQ/L)	01/02/91	105.00	103.00
Ca++	90-110 (MG/L)	01/02/91	96.00	95.00
PO4--	25-50 (MG/L)	01/02/91	40.00	45.60
SGOT	5-25 (UI/L)	01/02/91	16.00	20.00
SGPT	5-29 (UI/L)	01/02/91	14.00	23.00
GANMA GT	7-34 (UI/L)	01/02/91	16.00	
LDH	140-330 (UI/L)	01/02/91	198.00	275.00
ALK. PHOSPH.	30-90 (UI/L)	01/02/91	55.00	89.00
GLUCOSE	0.7-1.1 (G/L)	01/02/91	1.05	0.84
UREA	0.2-0.5 (G/L)	01/02/91	0.28	0.34
CREATININE	7-14 (MG/L)	01/02/91	9.10	12.20
URIC ACID	30-70 (MG/L)	01/02/91	38.00	32.00
TOT. BILIRUBIN	0-10 (MG/L)	01/02/91	4.50	8.30
TOT. PROTEINS	65-80 (G/L)	01/02/91	72.00	77.00
ALBUMINE	55-75 (X)	01/02/91	62.00	57.50
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.04	2.21
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	0.63	1.11
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/02/91	1.70	1.70
GLOBULINS ALPHA 2	6-12 (X)	01/02/91	9.00	10.30
GLOBULINS BETA	11-16 (X)	01/02/91	13.00	14.30
GLOBULINS GAMMA	12-17 (X)	01/02/91	14.30	16.20
TSH	0.2-6.5 (UUI/ML)	01/02/91	0.88	
T4	4.5-12 (UG/DL)	01/02/91	5.50	

1678

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOMETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 62 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/04/91		06/05/91		27/05/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/91	13.70		14.50		13.10	
HT	35-50 (%)	01/04/91	40.90		45.40		38.80	
RBC	3.8-5.4 (10 ⁶ /UL)	01/04/91	4.40		4.73		4.18	
HBC	4500-9000 (/UL)	01/04/91	9100.00	>	9260.00	>	9400.00	
HBC: N	2700-6300 (/MM3)	01/04/91	4623.00		4780.00		4952.00	
HBC: L	900-2700 (/MM3)	01/04/91	3276.00	>	3600.00	>>	3572.00	
HBC: E	45-360 (/MM3)	01/04/91	182.00		260.00		188.00	
HBC: M	90-540 (/MM3)	01/04/91	819.00	>>	580.00	>	664.00	
HBC: B	0-90 (/MM3)	01/04/91	0.00		40.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/04/91	290.00		349.00		350.00	
NA+	137-145 (MEQ/L)	01/04/91	139.00		143.00		139.00	
K+	3.8-5.6 (MEQ/L)	01/04/91	4.40		5.60		4.50	
CL-	98-108 (MEQ/L)	01/04/91	102.00		101.00		106.00	
Ca++	85-105 (MG/L)	01/04/91	89.00		99.00		86.00	
PO4--	25-42 (MG/L)	01/04/91	31.40		31.00		29.00	
SGOT	6-31 (UI/L)	01/04/91	14.00		12.00		12.00	
SGPT	5-35 (UI/L)	01/04/91	7.00		2.00	<	7.00	
GAMMA GT	9-37 (UI/L)	01/04/91	12.00		14.00		14.00	
LDH	230-460 (UI/L)	01/04/91	220.00	<	450.00		200.00	
ALK. PHOSPH.	41-133 (UI/L)	01/04/91	70.00		89.00		85.00	
GLUCOSE	0.7-1.1 (G/L)	01/04/91	0.80		0.80		0.75	
UREA	0.2-0.5 (G/L)	01/04/91	0.24		0.34		0.44	
CREATININE	5-13 (MG/L)	01/04/91	9.50		12.00		10.60	
URIC ACID	25-60 (MG/L)	01/04/91	37.00		49.00		35.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/04/91	5.00		3.00		6.00	
TOT. PROTEINS	63-78 (G/L)	01/04/91	75.00		83.00	>	70.00	
ALBUMINE	57-65 (%)	01/04/91	57.20		59.90		53.20	
TOT. CHOLEST.	1.5-2.3 (G/L)	01/04/91	1.89		1.96		1.89	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/04/91	0.90		1.26		1.32	
GLOBULINS ALPHA 1	2-4 (%)	01/04/91	3.50		3.90		4.00	
GLOBULINS ALPHA 2	6-10 (%)	01/04/91	10.80	>	10.70	>	11.60	
GLOBULINS BETA	8-12 (%)	01/04/91	13.00	>	10.80		12.80	
GLOBULINS GAMMA	12-19 (%)	01/04/91	15.50		14.70		18.40	

1679

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 63 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/05/91		03/06/91		22/06/91	
			value	(♣)	value	(♣)	value	(♣)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/05/91	14.40		14.70		13.80	
HT	40-55 (%)	01/05/91	46.10		45.30		40.50	
RBC	4.5-5.8 (10 ⁶ /UL)	01/05/91	5.07		5.32		4.85	
WBC	4500-9000 (/UL)	01/05/91	8500.00		8900.00		8300.00	
WBC: N	2700-6300 (/MM3)	01/05/91	5355.00		5340.00		4980.00	
WBC: L	900-2700 (/MM3)	01/05/91	2380.00		2581.00		2656.00	
WBC: E	45-360 (/MM3)	01/05/91	170.00		356.00		249.00	
WBC: M	90-540 (/MM3)	01/05/91	595.00	>	623.00	>	415.00	
WBC: B	0-90 (/MM3)	01/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/05/91	270.00		230.00		260.00	
NA+	137-145 (MEQ/L)	01/05/91	142.00		143.00		143.00	
K+	3.8-5.6 (MEQ/L)	01/05/91	4.80		4.30		4.20	
CL-	98-108 (MEQ/L)	01/05/91	107.00		110.00	>	109.00	
Ca++	85-105 (MG/L)	01/05/91	80.00	<	86.00		82.00	
PO4--	25-42 (MG/L)	01/05/91	32.00		26.00		29.00	
SGOT	6-37 (UI/L)	01/05/91	17.00		20.00		25.00	
SGPT	6-45 (UI/L)	01/05/91	18.00		20.00		16.00	
GAMMA GT	11-43 (UI/L)	01/05/91	19.00		21.00		17.00	
LDH	230-460 (UI/L)	01/05/91	230.00		350.00		360.00	
ALK. PHOSPH.	41-133 (UI/L)	01/05/91	127.00		131.00		106.00	
GLUCOSE	0.7-1.1 (G/L)	01/05/91	0.96		0.93		1.05	
UREA	0.2-0.5 (G/L)	01/05/91	0.40		0.38		0.42	
CREATININE	5-13 (MG/L)	01/05/91	11.30		10.70		10.30	
URIC ACID	25-65 (MG/L)	01/05/91	45.00		49.00		60.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/05/91	3.00		2.00		5.00	
TOT. PROTEINS	63-78 (G/L)	01/05/91	68.00		67.00		77.00	
ALBUMINE	57-65 (%)	01/05/91	54.50	<	57.70		59.30	
TOT. CHOLEST.	1.5-2.3 (G/L)	01/05/91	2.05		2.01		1.96	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/05/91	1.04		1.77	>	1.04	
GLOBULINS ALPHA 1	2-4 (%)	01/05/91	7.40	>>	3.40		3.90	
GLOBULINS ALPHA 2	6-10 (%)	01/05/91	9.20		11.50	>	10.00	
GLOBULINS BETA	8-12 (%)	01/05/91	13.80	>	12.20	>	12.00	
GLOBULINS GAMMA	12-19 (%)	01/05/91	15.10		15.20		14.80	

1680

(♣) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 64 Treatment: Placebo Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			08/03/91		03/04/91	
			value	(†)	value	(‡)
Laboratory test	Range value	Range data				
HB	11.5-15.5 (G/DL)	01/02/91	12.10		11.70	
HT	35-50 (%)	01/02/91	35.50		34.80 <	
RBC	3.8-5.4 (10 ⁶ /UL)	01/02/91	3.92		3.79 <	
MBC	4500-9000 (/UL)	01/02/91	10900.0 >		12800.0 >>	
MBC: N	2700-6300 (/UL)	01/02/91	4142.00		6784.00 >	
MBC: L	900-2700 (/UL)	01/02/91	4905.00 >>		5632.00 >>	
MBC: E	45-360 (/UL)	01/02/91	1417.00 >>		256.00 >>	
MBC: M	90-540 (/UL)	01/02/91	327.00		128.00	
MBC: B	0-90 (/UL)	01/02/91	109.00 >		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	275.00		326.00	
NA+	138-148 (MEQ/L)	01/02/91	142.50		143.00	
K+	3.8-5.6 (MEQ/L)	01/02/91	4.40		4.30	
CL-	95-108 (MEQ/L)	01/02/91	107.00		105.00	
Ca++	90-110 (MG/L)	01/02/91	100.00		94.00	
PO4--	25-50 (MG/L)	01/02/91	48.00		34.60	
SGOT	5-25 (UI/L)	01/02/91	14.00		21.00	
SGPT	5-29 (UI/L)	01/02/91	5.00		7.00	
GAMMA GT	6-22 (UI/L)	01/02/91	7.00		6.00	
LDH	140-330 (UI/L)	01/02/91	215.00		165.00	
ALK. PHOSPH.	30-100 (UI/L)	01/02/91	54.00		42.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.73		0.89	
UREA	0.2-0.5 (G/L)	01/02/91	0.46		0.56 >	
CREATININE	7-14 (MG/L)	01/02/91	9.30		9.50	
URIC ACID	30-70 (MG/L)	01/02/91	40.00			
TOT BILIRUBIN	0-10 (MG/L)	01/02/91	7.40		3.30	
TOT. PROTEINS	65-80 (G/L)	01/02/91	74.00		69.00	
ALBUMINE	55-75 (%)	01/02/91	59.70		52.70 <	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.81 >		2.33 >	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	0.98		0.67	
GLOBULINS ALPHA 1	1.5-4.5 (%)	01/02/91	3.10		3.40	
GLOBULINS ALPHA 2	6-12 (%)	01/02/91	8.60		8.40	
GLOBULINS BETA	11-16 (%)	01/02/91	15.20		16.80 >	
GLOBULINS GAMMA	12-17 (%)	01/02/91	13.40		18.70 >	
TSH	0.2-6.5 (UUI/ML)	01/02/91	0.81			
T4	4.5-12 (UG/DL)	01/02/91	8.58			

1681

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 65 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/09/91		07/10/91		28/10/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	10/08/91	12.90		12.00		12.60	
HT	40-55 (X)	10/08/91	40.20		39.80	<	40.50	
RBC	4.5-5.8 (10 ⁶ /UL)	10/08/91	6.57	>	6.50	>	6.26	
HBC	4500-9000 (/UL)	10/08/91	8800.00		11200.0	>	9400.00	
HBC: N	2700-6300 (/MM3)	10/08/91	5984.00		6384.00	>	5385.00	
HBC: L	900-2700 (/MM3)	10/08/91	2112.00		2912.00	>	2820.00	
HBC: E	45-360 (/MM3)	10/08/91	88.00		448.00	>	188.00	
HBC: M	90-540 (/MM3)	10/08/91	528.00		1344.00	>>	940.00	
HBC: B	0-90 (/MM3)	10/08/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	10/08/91	320.00		320.00		320.00	
NA+	137-145 (MEQ/L)	10/08/91	141.00		138.00		140.00	
K+	3.8-5.6 (MEQ/L)	10/08/91	5.00		4.90		5.00	
CL-	98-108 (MEQ/L)	10/08/91	109.00	>	107.00		108.00	
Ca ⁺⁺	85-105 (MG/L)	10/08/91	107.00	>	105.00		98.00	
PO4 ⁻⁻	25-42 (MG/L)	10/08/91	20.20	<<	26.00		30.00	
SGOT	6-37 (UI/L)	10/08/91	23.00		27.00		26.00	
SGPT	6-45 (UI/L)	10/08/91	19.00		24.00		20.00	
GAMMA GT	11-43 (UI/L)	10/08/91	17.00		18.00		22.00	
LDH	230-460 (UI/L)	10/08/91	320.00		330.00		340.00	
ALK. PHOSPH.	41-133 (UI/L)	10/08/91	144.00	>	153.00	>	141.00	
GLUCOSE	0.7-1.1 (G/L)	10/08/91	0.89		1.06		0.82	
UREA	0.2-0.5 (G/L)	10/08/91	0.19	<	0.29		0.30	
CREATININE	5-13 (MG/L)	10/08/91	9.90		10.50		10.40	
URIC ACID	25-65 (MG/L)	10/08/91	36.00		35.00		35.00	
TOT BILIRUBIN	0-10 (MG/L)	10/08/91	7.00		5.00		7.00	
TOT. PROTEINS	63-78 (G/L)	10/08/91	74.00		72.00		74.00	
ALBUMINE	57-65 (X)	10/08/91	55.30	<	51.70	<	48.70	
TOT. CHOLEST.	1.5-2.3 (G/L)	10/08/91	1.59		1.54		1.59	
TRIGLYCERIDES	0.5-1.6 (G/L)	10/08/91	0.69		1.01		0.81	
GLOBULINS ALPHA 1	2-6 (X)	10/08/91	4.20	>	3.90		4.20	
GLOBULINS ALPHA 2	6-10 (X)	10/08/91	7.80		8.90		10.20	
GLOBULINS BETA	8-12 (X)	10/08/91	10.20		10.80		11.00	
GLOBULINS GAMMA	12-19 (X)	10/08/91	22.50	>	24.70	>	25.90	

1682

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 66 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/06/91		01/07/91		22/07/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12.5-17.5 (G/DL)	01/02/91	15.00		15.10		15.40	
HT	40-55 (%)	01/02/91	43.70		44.00		46.90	
RBC	4.5-5.8 (10 ⁶ /UL)	01/02/91	4.62		4.75		4.99	
HBC	4500-9000 (/UL)	01/02/91	5200.00		4500.00		5100.00	
HBC: N	2700-6300 (/UL)	01/02/91	2600.00	<	2295.00	<	3060.00	
HBC: L	900-2700 (/UL)	01/02/91	2236.00		1935.00		1187.00	
HBC: E	45-360 (/UL)	01/02/91	208.00		45.00		51.00	
HBC: M	90-540 (/UL)	01/02/91	156.00		135.00		51.00	<
HBC: B	0-90 (/UL)	01/02/91	0.00		90.00		51.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	224.00		232.00		236.00	
NA+	138-148 (MEQ/L)	01/02/91	142.00		139.00		139.30	
K+	3.8-5.6 (MEQ/L)	01/02/91	4.13		4.38		4.32	
CL-	95-108 (MEQ/L)	01/02/91	104.00		100.00		105.00	
Ca++	90-110 (MG/L)	01/02/91	106.00		99.00		93.00	
PO4--	25-50 (MG/L)	01/02/91	52.50	>	38.20		31.40	
SGOT	5-25 (UI/L)	01/02/91	10.00		5.00		13.00	
SGPT	5-29 (UI/L)	01/02/91	15.00		15.00		13.00	
GAMMA GT	7-34 (UI/L)	01/02/91	27.00		30.00		24.00	
LDH	140-330 (UI/L)	01/02/91	181.00		187.00		195.00	
ALK. PHOSPH.	30-90 (UI/L)	01/02/91	57.00		75.00		72.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	1.12	>	1.04		1.09	
UREA	0.2-0.5 (G/L)	01/02/91	0.27		0.36		0.30	
CREATININE	7-14 (MG/L)	01/02/91	9.90		9.90		11.10	
URIC ACID	30-70 (MG/L)	01/02/91	72.00	>	86.00	>	91.00	>
TOT. BILIRUBIN	0-10 (MG/L)	01/02/91	6.10		6.10		5.70	
TOT. PROTEINS	65-80 (G/L)	01/02/91	68.00		75.00		72.00	
ALBUMINE	55-75 (%)	01/02/91	47.40	<	61.70		61.10	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.14		2.11		2.07	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	2.83	>>	2.49	>>	2.10	>>
GLOBULINS ALPHA 1	1.5-4.5 (%)	01/02/91	2.30		1.50		1.50	
GLOBULINS ALPHA 2	6-12 (%)	01/02/91	11.20		9.50		10.50	
GLOBULINS BETA	11-16 (%)	01/02/91	20.30	>	15.90		13.00	
GLOBULINS GAMMA	12-17 (%)	01/02/91	18.80	>	11.40	<	13.90	
TSH	0.2-6.5 (UUI/ML)	01/02/91	1.16					
T4	4.5-12 (UG/DL)	01/02/91	5.47					

1683

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 139 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			03/09/91
			value (⚡)
Laboratory test	Range value	Range date	
HB	12.5-17.5 (G/DL)	01/02/91	17.30
HT	40-55 (X)	01/02/91	50.50
RBC	4.5-5.8 (10 ⁶ /UL)	01/02/91	5.78
WBC	4500-9000 (/UL)	01/02/91	6600.00
WBC: N	2700-6300 (/UL)	01/02/91	3102.00
WBC: L	900-2700 (/UL)	01/02/91	970.00
WBC: E	45-360 (/UL)	01/02/91	396.00 >
WBC: M	90-540 (/UL)	01/02/91	132.00
WBC: B	0-90 (/UL)	01/02/91	0.00
PLATELETS	150-400 (10 ³ /UL)	01/02/91	191.00
NA+	138-148 (MEQ/L)	01/02/91	139.50
K+	3.8-5.6 (MEQ/L)	01/02/91	4.01
CL-	95-108 (MEQ/L)	01/02/91	100.00
Ca ⁺⁺	90-110 (MG/L)	01/02/91	97.00
PO4 ⁻⁻	25-50 (MG/L)	01/02/91	41.00
SGOT	5-25 (UI/L)	01/02/91	16.00
SGPT	5-29 (UI/L)	01/02/91	14.00
GAMMA GT	7-34 (UI/L)	01/02/91	14.00
LDH	140-330 (UI/L)	01/02/91	274.00
ALK. PHOSPH.	30-90 (UI/L)	01/02/91	63.00
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.78
UREA	0.2-0.5 (G/L)	01/02/91	0.48
CREATININE	7-14 (MG/L)	01/02/91	10.60
URIC ACID	30-70 (MG/L)	01/02/91	49.00
TOT BILIRUBIN	0-10 (MG/L)	01/02/91	6.70
TOT. PROTEINS	65-80 (G/L)	01/02/91	81.00 >
ALBUMINE	55-75 (X)	01/02/91	55.70
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.19
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	1.09
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/02/91	2.70
GLOBULINS ALPHA 2	6-12 (X)	01/02/91	8.90
GLOBULINS BETA	11-16 (X)	01/02/91	11.70
GLOBULINS GAMMA	12-17 (X)	01/02/91	21.00 >
TSH	0.2-6.5 (UUI/ML)	01/02/91	2.03
T4	4.5-12 (UG/DL)	01/02/91	8.79

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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 140 Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			10/09/91		03/10/91	
			value	(†)	value	(‡)
Laboratory test	Range value	Range date				
HB	12.5-17.5 (G/DL)	01/02/91	14.80		15.10	
HT	40-55 (X)	01/02/91	41.70		45.30	
RBC	4.5-5.8 (10 ⁶ /UL)	01/02/91	4.85		5.26	
WBC	4500-9000 (/UL)	01/02/91	4200.00	<	4700.00	
WBC: N	2700-6300 (/UL)	01/02/91	1932.00	<	2491.00	
WBC: L	900-2700 (/UL)	01/02/91	2058.00		1974.00	
WBC: E	45-360 (/UL)	01/02/91	84.00		141.00	
WBC: M	90-540 (/UL)	01/02/91	84.00	<	47.00	
WBC: B	0-90 (/UL)	01/02/91	42.00		47.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	150.00		152.00	
NA+	138-148 (MEQ/L)	01/02/91	143.00		141.50	
K+	3.8-5.6 (MEQ/L)	01/02/91	4.65		4.95	
CL-	95-108 (MEQ/L)	01/02/91	102.00		100.00	
Ca++	90-110 (MG/L)	01/02/91	101.00		92.00	
PO4--	25-50 (MG/L)	01/02/91	40.50		37.60	
SGOT	5-25 (UI/L)	01/02/91	12.00		12.00	
SGPT	5-29 (UI/L)	01/02/91	10.00		12.00	
GAMMA GT	7-34 (UI/L)	01/02/91	12.00		10.00	
LDH	140-330 (UI/L)	01/02/91	177.00		204.00	
ALK. PHOSPH.	30-90 (UI/L)	01/02/91	37.00		51.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.88		0.90	
UREA	0.2-0.5 (G/L)	01/02/91	0.30		0.40	
CREATININE	7-14 (MG/L)	01/02/91	13.60		11.20	
URIC ACID	30-70 (MG/L)	01/02/91	51.00		59.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/02/91	7.20		8.30	
TOT. PROTEINS	65-80 (G/L)	01/02/91	65.00		71.00	
ALBUMINE	55-75 (X)	01/02/91	62.50		61.60	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	1.58		1.78	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	0.68		0.88	
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/02/91	3.30		1.90	
GLOBULINS ALPHA 2	6-12 (X)	01/02/91	7.60		5.30	
GLOBULINS BETA	11-16 (X)	01/02/91	8.90	<	10.00	
GLOBULINS GAMMA	12-17 (X)	01/02/91	17.70	>	21.20	
TSH	0.2-6.5 (UUI/ML)	01/02/91	0.51			
T4	4.5-12 (UG/DL)	01/02/91	5.85			

1685

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 141 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/09/91		23/10/91		14/11/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-15.5 (G/DL)	01/02/91	12.20		12.30		12.70	
HT	35-50 (%)	01/02/91	36.20		36.60		37.90	
RBC	3.8-5.4 (10 ⁶ /UL)	01/02/91	4.09		4.02		4.25	
WBC	4500-9000 (/UL)	01/02/91	5200.00		5900.00		5500.00	
WBC: N	2700-6300 (/UL)	01/02/91	2392.00	<	3658.00		3190.00	
WBC: L	900-2700 (/UL)	01/02/91	2600.00		2124.00		2035.00	
WBC: E	45-360 (/UL)	01/02/91	52.00		0.00	<	165.00	
WBC: M	90-540 (/UL)	01/02/91	156.00		59.00	<	110.00	
WBC: B	0-90 (/UL)	01/02/91	0.00		59.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	198.00		197.00		226.00	
NA+	138-148 (MEQ/L)	01/02/91	141.80		144.00		143.50	
K+	3.8-5.6 (MEQ/L)	01/02/91	4.08		4.10		4.30	
CL-	95-108 (MEQ/L)	01/02/91	105.00		104.00		106.00	
Ca++	90-110 (MG/L)	01/02/91	99.00		92.00		97.00	
PO4--	25-50 (MG/L)	01/02/91	45.00		42.80		46.00	
SGOT	5-25 (UI/L)	01/02/91	8.00		10.00		9.00	
SGPT	5-29 (UI/L)	01/02/91	6.00		8.00		8.00	
GAMMA GT	6-22 (UI/L)	01/02/91	10.00		13.00		11.00	
LDH	140-330 (UI/L)	01/02/91	207.00		204.00		194.00	
ALK. PHOSPH.	30-100 (UI/L)	01/02/91	66.00		50.00		42.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	1.04		1.01		1.04	
UREA	0.2-0.5 (G/L)	01/02/91	0.47		0.31		0.36	
CREATININE	7-14 (MG/L)	01/02/91	10.50		9.30		10.00	
URIC ACID	30-70 (MG/L)	01/02/91	28.00	<	39.00		37.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/02/91	5.30		4.60			
TOT. PROTEINS	65-80 (G/L)	01/02/91	64.00	<	64.00	<	65.00	
ALBUMINE	55-75 (%)	01/02/91	63.90		59.80		67.20	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.57	>	1.99		2.28	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	0.62		0.84		0.71	
GLOBULINS ALPHA 1	1.5-4.5 (%)	01/02/91	1.00	<<	2.70		2.80	
GLOBULINS ALPHA 2	6-12 (%)	01/02/91	7.70		9.50		7.10	
GLOBULINS BETA	11-16 (%)	01/02/91	14.30		15.80		11.60	
GLOBULINS GAMMA	12-17 (%)	01/02/91	13.10		12.20		11.30	
TSH	0.2-6.5 (UUI/ML)	01/02/91	0.88					
T4	4.5-12 (UG/DL)	01/02/91	5.52					

1686

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 142 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			14/11/91
			value (†)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	11/09/91	13.10
HT	35-50 (X)	11/09/91	38.20
RBC	3.8-5.4 (10 ⁶ /UL)	11/09/91	4.66
WBC	4500-9000 (/UL)	11/09/91	6900.00
WBC: N	45-70 (X)	11/09/91	53.00
WBC: L	20-40 (X)	11/09/91	34.00
WBC: E	1-2 (X)	11/09/91	4.00 >>
WBC: M	2-8 (X)	11/09/91	9.00 >
WBC: B	0-1 (X)	11/09/91	0.00
PLATELETS	150-400 (10 ³ /UL)	11/09/91	250.00
NA+	137-145 (MEQ/L)	11/09/91	137.00
K+	3.8-5.6 (MEQ/L)	11/09/91	4.10
CL-	98-108 (MEQ/L)	11/09/91	107.00
Ca++	85-105 (MG/L)	11/09/91	96.00
PO4--	25-42 (MG/L)	11/09/91	32.00
SGOT	6-31 (UI/L)	11/09/91	15.00
SGPT	5-35 (UI/L)	11/09/91	9.00
GAMMA GT	9-37 (UI/L)	11/09/91	19.00
LDH	230-460 (UI/L)	11/09/91	220.00 <
ALK. PHOSPH.	41-133 (UI/L)	11/09/91	99.00
GLUCOSE	0.7-1.1 (G/L)	11/09/91	0.72
UREA	0.2-0.5 (G/L)	11/09/91	0.18 <
CREATININE	5-13 (MG/L)	11/09/91	8.40
URIC ACID	25-60 (MG/L)	11/09/91	28.00
TOT BILIRUBIN	0-10 (MG/L)	11/09/91	7.00
TOT. PROTEINS	63-78 (G/L)	11/09/91	72.00
ALBUMINE	57-65 (X)	11/09/91	50.50 <
TOT. CHOLEST.	1.5-2.3 (G/L)	11/09/91	2.26
TRIGLYCERIDES	0.5-1.6 (G/L)	11/09/91	0.78
GLOBULINS ALPHA 1	2-4 (X)	11/09/91	5.90 >>
GLOBULINS ALPHA 2	6-10 (X)	11/09/91	10.50 >
GLOBULINS BETA	8-12 (X)	11/09/91	12.30 >
GLOBULINS GAMMA	12-19 (X)	11/09/91	20.80 >

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(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 143 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 35
			14/04/92	20/05/92
			value (♣)	value (♣)
Laboratory test	Range value	Range date		
HB	11.5-15.5 (G/DL)	01/02/91	13.20	13.30
HT	35-50 (X)	01/02/91	40.50	38.50
RBC	3.8-5.4 (10 ⁶ /UL)	01/02/91	4.40	4.48
WBC	4500-9000 (/UL)	01/02/91	4900.00	5400.00
WBC: N	2700-6300 (/UL)	01/02/91	2499.00	2322.00
WBC: L	900-2700 (/UL)	01/02/91	2156.00	2700.00
WBC: E	45-360 (/UL)	01/02/91	98.00	54.00
WBC: M	90-540 (/UL)	01/02/91	147.00	270.00
WBC: B	0-90 (/UL)	01/02/91	0.00	54.00
PLATELETS	150-400 (10 ³ /UL)	01/02/91	211.00	240.00
NA+	138-148 (MEQ/L)	01/02/91	140.00	138.00
K+	3.8-5.6 (MEQ/L)	01/02/91	4.30	4.40
CL-	95-108 (MEQ/L)	01/02/91	106.00	103.00
Ca++	90-110 (MG/L)	01/02/91	90.00	96.00
PO4--	25-50 (MG/L)	01/02/91	45.90	39.00
SGOT	5-25 (UI/L)	01/02/91	11.00	8.00
SGPT	5-29 (UI/L)	01/02/91	8.00	7.00
GAMMA GT	6-22 (UI/L)	01/02/91	10.00	10.00
LDH	140-330 (UI/L)	01/02/91	126.00	114.00
ALK. PHOSPH.	30-100 (UI/L)	01/02/91	55.00	49.00
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.84	0.82
UREA	0.2-0.5 (G/L)	01/02/91	0.29	0.24
CREATININE	7-14 (MG/L)	01/02/91	10.00	9.60
URIC ACID	30-70 (MG/L)	01/02/91	33.00	51.00
TOT BILIRUBIN	0-10 (MG/L)	01/02/91	2.00	4.00
TOT. PROTEINS	65-80 (G/L)	01/02/91	64.00	63.00
ALBUMINE	55-75 (X)	01/02/91	65.80	65.10
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.32	2.12
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	1.30	1.42
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/02/91	2.80	2.80
GLOBULINS ALPHA 2	6-12 (X)	01/02/91	7.60	7.60
GLOBULINS BETA	11-16 (X)	01/02/91	10.70	10.10
GLOBULINS GAMMA	12-17 (X)	01/02/91	13.10	14.40
TSH	0.2-6.5 (UUI/ML)	01/02/91	0.90	
T4	4.5-12 (UG/DL)	01/02/91	8.30	

1688

(♣) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 144 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 42	
			04/06/92		21/07/92	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	11.5-15.5 (G/DL)	01/02/91	12.80		13.50	
HT	35-50 (%)	01/02/91	38.00		40.20	
RBC	3.8-5.4 (10 ⁶ /UL)	01/02/91	4.29		4.48	
WBC	4500-9000 (/UL)	01/02/91	10700.0 >		10700.0 >	
WBC: N	2700-6300 (/UL)	01/02/91	6985.00 >		6099.00 >	
WBC: L	900-2700 (/UL)	01/02/91	3317.00 >		4066.00 >>	
WBC: E	45-360 (/UL)	01/02/91	214.00		107.00	
WBC: M	90-540 (/UL)	01/02/91	214.00		428.00	
WBC: B	0-90 (/UL)	01/02/91	0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	156.00		138.00 <	
NA+	138-148 (MEQ/L)	01/02/91	138.00		138.00	
K+	3.8-5.6 (MEQ/L)	01/02/91	4.10		3.60 <	
CL-	95-108 (MEQ/L)	01/02/91	104.00		103.00	
Ca++	90-110 (MG/L)	01/02/91	88.00 <		95.00	
PO4--	25-50 (MG/L)	01/02/91	28.00		35.00	
SGOT	5-25 (UI/L)	01/02/91	10.00		14.00	
SGPT	5-29 (UI/L)	01/02/91	7.00		8.00	
GAMMA GT	6-22 (UI/L)	01/02/91	14.00		18.00	
LDH	140-330 (UI/L)	01/02/91	157.00		193.00	
ALK. PHOSPH.	30-100 (UI/L)	01/02/91	58.00		56.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.83		0.60 <	
UREA	0.2-0.5 (G/L)	01/02/91	0.16 <		0.22	
CREATININE	7-14 (MG/L)	01/02/91	7.70		9.00	
URIC ACID	30-70 (MG/L)	01/02/91	42.00		52.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/02/91	4.00		6.00	
TOT. PROTEINS	65-80 (G/L)	01/02/91	67.00		73.00	
ALBUMINE	55-75 (%)	01/02/91	57.20		63.00	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	1.65		1.58	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	0.67		0.65	
GLOBULINS ALPHA 1	1.5-4.5 (%)	01/02/91	1.10 <		1.10 <	
GLOBULINS ALPHA 2	6-12 (%)	01/02/91	9.80		8.00	
GLOBULINS BETA	11-16 (%)	01/02/91	9.30 <		8.90 <	
GLOBULINS GAMMA	12-17 (%)	01/02/91	22.60 >>		19.00 >	

1689

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/1 Patient: 451 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			16/01/92
			value (€)
Laboratory test	Range value	Range date	
HB	11.5-15.5 (G/DL)	01/02/91	13.20
HT	35-50 (%)	01/02/91	39.50
RBC	3.8-5.4 (10 ⁶ /UL)	01/02/91	4.52
WBC	4500-9000 (/UL)	01/02/91	4000.00 <
WBC: N	2700-6300 (/UL)	01/02/91	1760.00 <<
WBC: L	900-2700 (/UL)	01/02/91	2160.00
WBC: E	45-360 (/UL)	01/02/91	0.00 <
WBC: M	90-540 (/UL)	01/02/91	80.00 <
WBC: B	0-90 (/UL)	01/02/91	0.00
PLATELETS	150-400 (10 ³ /UL)	01/02/91	206.00
NA+	138-148 (MEQ/L)	01/02/91	140.20
K+	3.8-5.6 (MEQ/L)	01/02/91	4.20
CL-	95-108 (MEQ/L)	01/02/91	105.00
Ca++	90-110 (MG/L)	01/02/91	100.00
PO4--	25-50 (MG/L)	01/02/91	31.00
SGOT	5-25 (UI/L)	01/02/91	20.00
SGPT	5-29 (UI/L)	01/02/91	14.00
GAMMA GT	6-22 (UI/L)	01/02/91	14.00
LDH	140-330 (UI/L)	01/02/91	234.00
ALK. PHOSPH.	30-100 (UI/L)	01/02/91	50.00
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.82
UREA	0.2-0.5 (G/L)	01/02/91	0.39
CREATININE	7-14 (MG/L)	01/02/91	7.10
URIC ACID	30-70 (MG/L)	01/02/91	38.00
TOT BILIRUBIN	0-10 (MG/L)	01/02/91	4.50
TOT. PROTEINS	65-80 (G/L)	01/02/91	76.00
ALBUMINE	55-75 (%)	01/02/91	58.40
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.30 >
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	1.02
GLOBULINS ALPHA 1	1.5-4.5 (%)	01/02/91	4.50
GLOBULINS ALPHA 2	6-12 (%)	01/02/91	9.80
GLOBULINS BETA	11-16 (%)	01/02/91	12.00
GLOBULINS GAMMA	12-17 (%)	01/02/91	15.30
TSH	0.2-6.5 (UUI/ML)	01/02/91	1.22
T4	4.5-12 (UG/DL)	01/02/91	6.80

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/1 Patient: 452 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/01/92		12/02/92		09/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12.5-17.5 (G/DL)	01/02/91	14.80		14.30		13.80	
HT	40-55 (X)	01/02/91	41.70		44.90		42.20	
RBC	4.5-5.8 (10 ⁶ /UL)	01/02/91	4.92		4.97		4.67	
HBC	4500-9000 (/UL)	01/02/91	6500.00		5300.00		4800.00	
HBC: N	2700-6300 (/UL)	01/02/91	2730.00		3021.00		2304.00 <	
HBC: L	900-2700 (/UL)	01/02/91	3185.00 >		2014.00		2256.00	
HBC: E	45-360 (/UL)	01/02/91	195.00		159.00		144.00	
HBC: M	90-540 (/UL)	01/02/91	390.00		0.00 <		96.00	
HBC: B	0-90 (/UL)	01/02/91	0.00		106.00 >		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	209.00		190.00		178.00	
NA+	138-148 (MEQ/L)	01/02/91	141.70		140.00		140.00	
K+	3.8-5.6 (MEQ/L)	01/02/91	3.90		3.90		3.70 <	
CL-	95-108 (MEQ/L)	01/02/91	104.00		102.00		104.00	
Ca++	90-110 (MG/L)	01/02/91	102.00		100.00		97.00	
PO4--	25-50 (MG/L)	01/02/91	34.00		45.00		47.00	
SGOT	5-25 (UI/L)	01/02/91	27.00 >		16.00		16.00	
SGPT	5-29 (UI/L)	01/02/91	26.00		21.00		25.00	
GAMMA GT	7-34 (UI/L)	01/02/91	185.00 >>		72.00 >>		46.00 >	
LDH	140-330 (UI/L)	01/02/91	231.00		198.00		189.00	
ALK. PHOSPH.	30-90 (UI/L)	01/02/91	104.00 >		87.00		85.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.96		0.98		1.67 >>	
UREA	0.2-0.5 (G/L)	01/02/91	0.23		0.45		0.34	
CREATININE	7-14 (MG/L)	01/02/91	5.70 <		8.60		8.40	
URIC ACID	30-70 (MG/L)	01/02/91	71.00 >		47.00		41.00	
TOT BILIRUBIN	0-10 (MG/L)	01/02/91	6.50		5.10		4.00	
TOT. PROTEINS	65-80 (G/L)	01/02/91	80.00		78.00		72.00	
ALBUMINE	55-75 (X)	01/02/91	58.60		69.40		63.00	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	3.28 >>		2.27 >		2.01	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	3.45 >>		2.14 >>		1.55	
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/02/91	9.60 >>		2.20		3.20	
GLOBULINS ALPHA 2	6-12 (X)	01/02/91	9.30		6.80		8.40	
GLOBULINS BETA	11-16 (X)	01/02/91	12.10		11.00		13.70	
GLOBULINS GAMMA	12-17 (X)	01/02/91	10.40 <		10.60 <		11.70 <	
TSH	0.2-6.5 (UUI/ML)	01/02/91	3.71					
T4	4.5-12 (UG/DL)	01/02/91	6.40					

1691

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 453 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/01/92		19/02/92		11/03/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11.5-15.5 (G/DL)	01/02/91	12.60		12.70		11.90	
HT	35-50 (X)	01/02/91	36.20		40.20		37.80	
RBC	3.8-5.4 (10 ⁶ /UL)	01/02/91	4.32		4.54		4.27	
HBC	4500-9000 (/UL)	01/02/91	5700.00		5600.00		4800.00	
HBC: N	2700-6300 (/UL)	01/02/91	2508.00	<	2464.00	<	1920.00	
HBC: L	900-2700 (/UL)	01/02/91	3021.00	>	2800.00	>	2544.00	
HBC: E	45-360 (/UL)	01/02/91	114.00		168.00		144.00	
HBC: H	90-540 (/UL)	01/02/91	57.00	<	168.00		144.00	
HBC: B	0-90 (/UL)	01/02/91	0.00		0.00		48.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	253.00		275.00		243.00	
NA+	138-148 (MEQ/L)	01/02/91	142.80		141.00		141.00	
K+	3.8-5.6 (MEQ/L)	01/02/91	4.40		4.20		4.20	
CL-	95-108 (MEQ/L)	01/02/91	110.00	>	99.00		105.00	
Ca++	90-110 (MG/L)	01/02/91	91.00		91.00		91.00	
PO4--	25-50 (MG/L)	01/02/91	35.00		37.40		44.00	
SGOT	5-25 (UI/L)	01/02/91	19.00		23.00		24.00	
SGPT	5-29 (UI/L)	01/02/91	19.00		23.00		24.00	
GAMMA GT	6-22 (UI/L)	01/02/91	14.00		25.00	>	17.00	
LDH	140-330 (UI/L)	01/02/91	202.00		197.00		208.00	
ALK. PHOSPH.	30-100 (UI/L)	01/02/91	28.00	<	40.00		46.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	1.19	>	1.18	>	1.17	
UREA	0.2-0.5 (G/L)	01/02/91	0.21		0.28		0.26	
CREATININE	7-14 (MG/L)	01/02/91	5.90	<	6.10	<	6.40	
URIC ACID	30-70 (MG/L)	01/02/91	24.00	<	39.00		29.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/02/91	4.00		3.20		4.00	
TOT. PROTEINS	65-80 (G/L)	01/02/91	74.00		80.00		73.00	
ALBUMINE	55-75 (X)	01/02/91	67.00		64.70		63.10	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	1.46	<	2.28	>	2.14	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	0.88		1.78	>	1.37	
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/02/91	1.80		1.80		1.80	
GLOBULINS ALPHA 2	6-12 (X)	01/02/91	6.20		7.40		7.60	
GLOBULINS BETA	11-16 (X)	01/02/91	13.70		15.10		15.10	
GLOBULINS GAMMA	12-17 (X)	01/02/91	11.30	<	11.00	<	12.40	
TSH	0.2-6.5 (UUI/ML)	01/02/91	1.56					
T4	4.5-12 (UG/DL)	01/02/91	7.40					

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 454 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/02/92		09/03/92		01/04/92	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	12.5-17.5 (G/DL)	01/02/91	14.90		15.00		15.10	
HT	40-55 (%)	01/02/91	45.60		45.20		45.90	
RBC	4.5-5.8 (10 ⁶ /UL)	01/02/91	4.44 <		4.57		4.60	
HBC	4500-9000 (/UL)	01/02/91	5600.00		4600.00		5800.00	
HBC: N	2700-6300 (/UL)	01/02/91	2296.00 <		2346.00 <		2494.00 <	
HBC: L	900-2700 (/UL)	01/02/91	3192.00 >		2024.00		3016.00 >	
HBC: E	45-360 (/UL)	01/02/91	112.00		92.00		116.00	
HBC: M	90-540 (/UL)	01/02/91	0.00 <		92.00		174.00	
HBC: B	0-90 (/UL)	01/02/91	0.00		46.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	132.00 <		108.00 <		115.00 <	
NA+	138-148 (MEQ/L)	01/02/91	138.00		139.00		138.00	
K+	3.8-5.6 (MEQ/L)	01/02/91	4.10		4.00		3.90	
CL-	95-108 (MEQ/L)	01/02/91	104.00		104.00		101.00	
Ca++	90-110 (MG/L)	01/02/91	98.00		102.00		95.00	
PO4--	25-50 (MG/L)	01/02/91	41.00		40.00		38.00	
SGOT	5-25 (UI/L)	01/02/91	16.00		13.00		10.00	
SGPT	5-29 (UI/L)	01/02/91	19.00		14.00		14.00	
GAMMA GT	7-34 (UI/L)	01/02/91	21.00		17.00		19.00	
LDH	140-330 (UI/L)	01/02/91	228.00		267.00		212.00	
ALK. PHOSPH.	30-90 (UI/L)	01/02/91	39.00		38.00		33.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	1.18 >		1.22 >		1.28 >	
UREA	0.2-0.5 (G/L)	01/02/91	0.59 >		0.50		0.47	
CREATININE	7-14 (MG/L)	01/02/91	10.20		8.40		10.60	
URIC ACID	30-70 (MG/L)	01/02/91	32.00		27.00 <		32.00	
TOT. BILIRUBIN	0-10 (MG/L)	01/02/91	8.30		8.00		10.00	
TOT. PROTEINS	65-80 (G/L)	01/02/91	78.00		77.00		75.00	
ALBUMINE	55-75 (%)	01/02/91	65.60		64.10		65.60	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	1.76		1.80		1.76	
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	1.93 >		1.21		1.39	
GLOBULINS ALPHA 1	1.5-4.5 (%)	01/02/91	2.80		2.70		2.90	
GLOBULINS ALPHA 2	6-12 (%)	01/02/91	5.80 <		6.30		6.20	
GLOBULINS BETA	11-16 (%)	01/02/91	11.90		12.60		12.40	
GLOBULINS GAMMA	12-17 (%)	01/02/91	13.90		14.30		12.90	
TSH	0.2-6.5 (UUI/ML)	01/02/91	1.90					
T4	4.5-12 (UG/DL)	01/02/91	5.10					

1693

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/1 Patient: 455 Treatment: Placebo Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			03/03/92	01/04/92
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	11.5-15.5 (G/DL)	01/02/91	19.10	14.00
HT	35-50 (%)	01/02/91	40.20	43.90
RBC	3.8-5.4 (10 ⁶ /UL)	01/02/91	4.14	4.47
WBC	4500-9000 (/UL)	01/02/91	8000.00	5000.00
WBC: N	2700-6300 (/UL)	01/02/91	5360.00	2300.00
WBC: L	900-2700 (/UL)	01/02/91	2240.00	2550.00
WBC: E	45-360 (/UL)	01/02/91	160.00	100.00
WBC: M	90-540 (/UL)	01/02/91	240.00	50.00
WBC: B	0-90 (/UL)	01/02/91	0.00	0.00
PLATELETS	150-400 (10 ³ /UL)	01/02/91	247.00	264.00
NA+	138-148 (MEQ/L)	01/02/91	140.00	139.00
K+	3.8-5.6 (MEQ/L)	01/02/91	4.30	4.10
CL-	95-108 (MEQ/L)	01/02/91	104.00	103.00
Ca++	90-110 (MG/L)	01/02/91	94.00	103.00
PO4--	25-50 (MG/L)	01/02/91	38.40	32.00
SGOT	5-25 (UI/L)	01/02/91	19.00	20.00
SGPT	5-29 (UI/L)	01/02/91	11.00	12.00
GAMMA GT	6-22 (UI/L)	01/02/91	10.00	9.00
LDH	140-350 (UI/L)	01/02/91	228.00	207.00
ALK. PHOSPH.	30-100 (UI/L)	01/02/91	64.00	48.00
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.90	1.07
UREA	0.2-0.5 (G/L)	01/02/91	0.47	0.48
CREATININE	7-14 (MG/L)	01/02/91	10.10	8.50
URIC ACID	30-70 (MG/L)	01/02/91	29.00	29.00
TOT BILIRUBIN	0-10 (MG/L)	01/02/91	5.00	6.00
TOT. PROTEINS	65-80 (G/L)	01/02/91	71.00	64.00
ALBUMINE	55-75 (%)	01/02/91	68.00	69.90
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.20	2.38
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	0.51	0.52
GLOBULINS ALPHA 1	1.5-4.5 (%)	01/02/91	2.70	3.10
GLOBULINS ALPHA 2	6-12 (%)	01/02/91	6.90	5.70
GLOBULINS BETA	11-16 (%)	01/02/91	10.40	9.30
GLOBULINS GAMMA	12-17 (%)	01/02/91	12.00	12.00
TSH	0.2-6.5 (UUI/ML)	01/02/91	1.60	
T4	4.5-12 (UG/DL)	01/02/91	5.40	

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/1 Patient: 456 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	
			18/03/92	
			value	(*)
Laboratory test	Range value	Range date		
HB	11.5-15.5 (G/DL)	01/02/91	12.70	
HT	35-50 (%)	01/02/91	38.80	
RBC	3.8-5.4 (10 ⁶ /UL)	01/02/91	4.04	
WBC	4500-9000 (/UL)	01/02/91	5600.00	
WBC: N	2700-6300 (/UL)	01/02/91	2576.00	<
WBC: L	900-2700 (/UL)	01/02/91	2856.00	>
WBC: E	45-360 (/UL)	01/02/91	56.00	
WBC: M	90-540 (/UL)	01/02/91	112.00	
WBC: B	0-90 (/UL)	01/02/91	0.00	
PLATELETS	150-400 (10 ³ /UL)	01/02/91	204.00	
NA+	138-148 (MEQ/L)	01/02/91	137.00	<
K+	3.8-5.6 (MEQ/L)	01/02/91	4.00	
CL-	95-108 (MEQ/L)	01/02/91	99.00	
Ca++	90-110 (MG/L)	01/02/91	95.00	
PO4--	25-50 (MG/L)	01/02/91	32.00	
SGOT	5-25 (UI/L)	01/02/91	10.00	
SGPT	5-29 (UI/L)	01/02/91	14.00	
GAMMA GT	6-22 (UI/L)	01/02/91	10.00	
LDH	140-330 (UI/L)	01/02/91	184.00	
ALK. PHOSPH.	30-100 (UI/L)	01/02/91	35.00	
GLUCOSE	0.7-1.1 (G/L)	01/02/91	0.84	
UREA	0.2-0.5 (G/L)	01/02/91	0.38	
CREATININE	7-14 (MG/L)	01/02/91	7.50	
URIC ACID	30-70 (MG/L)	01/02/91	41.00	
TOT BILIRUBIN	0-10 (MG/L)	01/02/91	5.00	
TOT. PROTEINS	65-80 (G/L)	01/02/91	65.00	
ALBUMINE	55-75 (%)	01/02/91	64.20	
TOT. CHOLEST.	1.5-2.2 (G/L)	01/02/91	2.80	>
TRIGLYCERIDES	0.5-1.6 (G/L)	01/02/91	0.92	
GLOBULINS ALPHA 1	1.5-4.5 (%)	01/02/91	2.20	
GLOBULINS ALPHA 2	6-12 (%)	01/02/91	6.80	
GLOBULINS BETA	11-16 (%)	01/02/91	11.10	
GLOBULINS GAMMA	12-17 (%)	01/02/91	15.70	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/2 Patient: 65/A Treatment: Reboxetina Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/01/91		19/02/91		12/03/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	120-160 (G/L)	01/01/91	129.00		134.00		123.00	
HT	0.37-0.47 (L/L)	01/01/91	0.40		0.41		0.39	
RBC	4.1-5.3 (10 ¹² /L)	01/01/91	4.24		4.53		4.22	
WBC	4-10 (10 ⁹ /L)	01/01/91	3.40	<	4.00		4.50	
WBC: N	45-74 (%)	01/01/91	53.00		60.00		64.00	
WBC: L	16-45 (%)	01/01/91	40.00		36.00		30.00	
WBC: E	0-7 (%)	01/01/91	2.00		0.00		0.00	
WBC: M	4-10 (%)	01/01/91	5.00		4.00		6.00	
WBC: B	0-2 (%)	01/01/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	01/01/91	261.00		291.00		307.00	
NA+	135-145 (MMOL/L)	01/01/91	142.00		142.00		144.00	
K+	3.5-5 (MMOL/L)	01/01/91	4.20		4.20		4.30	
CL-	95-105 (MMOL/L)	01/01/91	102.00		101.00		101.00	
Ca++	2.1-2.5 (MMOL/L)	01/01/91	2.48		2.38		2.45	
SGOT	5-30 (UI/L)	01/01/91	10.00		12.00		15.00	
SGPT	5-40 (UI/L)	01/01/91	4.00	<	8.00		14.00	
GAMMA GT	6-28 (UI/L)	01/01/91	6.00		5.00	<	6.00	
LDH	140-280 (UI/L)	01/01/91	200.00		175.00		175.00	
ALK. PHOSPH.	30-100 (UI/L)	01/01/91	40.00		41.00		48.00	
GLUCOSE	3.4-5.6 (MMOL/L)	01/01/91	3.70		4.10		4.80	
UREA	2.5-6.7 (MMOL/L)	01/01/91	3.90		4.10		4.30	
CREATININE	70-115 (UMOL/L)	01/01/91	82.00		75.00		77.00	
URIC ACID	235-360 (UMOL/L)	01/01/91	221.00	<	273.00		210.00	<
TOT BILIRUBIN	4-20 (UMOL/L)	01/01/91	8.00		11.00		6.00	
DIR BILIRUBIN	0-10 (UMOL/L)	01/01/91	7.00		5.00		6.00	
TOT. PROTEINS	60-75 (G/L)	01/01/91	65.00		71.00		68.00	
ALBUMINE	37-42 (G/L)	01/01/91	44.40	>	42.70	>	43.40	>
TOT. CHOLEST.	4-6 (MMOL/L)	01/01/91	4.41		5.27		5.52	
TRIGLYCERIDES	0.6-1.7 (MMOL/L)	01/01/91	0.60		0.88		0.70	
GLOBULINS ALPHA 1	1-3 (G/L)	01/01/91	2.30		3.40	>	2.90	
GLOBULINS ALPHA 2	4-7 (G/L)	01/01/91	4.70		6.10		5.40	
GLOBULINS BETA	5-8 (G/L)	01/01/91	5.90		8.60	>	7.80	
GLOBULINS GAMMA	8-12 (G/L)	01/01/91	7.70	<	10.20		8.50	
TSH	0.3-5 (UI/L)	01/01/91	0.95					
T4	8-18 (PMOL/L)	01/01/91	16.40					

1696

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/3 Patient: 67 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/07/91		07/08/91		28/08/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/100ML)	23/04/91	15.80		14.80		13.30	
HT	40-50 (X)	23/04/91	45.80		43.10		38.70 <	
RBC	4.2-4.9 (10 ⁶ /MM ³)	23/04/91	5.40 >		5.16 >		4.69	
WBC	4-10 (10 ³ /MM ³)	23/04/91	7.90		8.70		9.20	
WBC: N	2-7.5 (10 ³ /MM ³)	23/04/91	5.60		5.70		5.10	
WBC: L	1.5-4 (10 ³ /MM ³)	23/04/91	2.00		2.10		3.10	
WBC: E	0.04-0.4 (10 ³ /MM ³)	23/04/91			0.40		0.00 <	
WBC: M	0.2-0.8 (10 ³ /MM ³)	23/04/91	0.20		0.50		0.90 >	
PLATELETS	150-400 (10 ³ /MM ³)	23/04/91	188.00		174.00		166.00	
NA+	135-145 (MEQ/L)	23/04/91	142.00		142.00		145.00	
K+	3.5-5 (MEQ/L)	23/04/91	4.60		3.90		4.10	
CL-	95-105 (MEQ/L)	23/04/91	106.00 >		108.00 >		109.00 >	
Ca++	85-105 (MG/L)	23/04/91	94.00		92.00		92.00	
PO4--	22-45 (MG/L)	23/04/91	40.00		42.00		42.00	
SGOT	8-30 (UI/L)	23/04/91	17.00		16.00		10.00	
SGPT	7-46 (UI/L)	23/04/91	31.00		30.00		15.00	
GAMMA GT	5-36 (UI/L)	23/04/91	34.00		18.00		19.00	
LDH	260-330 (UI/L)	23/04/91			150.00 <		148.00 <	
ALK. PHOSPH.	80-220 (UI/L)	23/04/91	123.00		103.00		100.00	
GLUCOSE	0.65-1.1 (G/L)	23/04/91	0.90		0.70		0.83	
UREA	0.15-0.45 (G/L)	23/04/91	0.31		0.29		0.32	
CREATININE	3-15 (MG/L)	23/04/91	10.00		9.00		10.00	
URIC ACID	25-60 (MG/L)	23/04/91	73.00 >		70.00 >		72.00 >	
TOT BILIRUBIN	1.5-12 (MG/L)	23/04/91	3.00		4.00		3.00	
DIR BILIRUBIN	0-3 (MG/L)	23/04/91	1.00		1.00		1.00	
TOT. PROTEINS	60-80 (G/L)	23/04/91	66.00		65.00		57.00 <	
ALBUMINE	33-50 (G/L)	23/04/91	45.00		45.00		43.00	
TOT. CHOLEST.	1.3-2.1 (G/L)	23/04/91	2.09		2.02		1.77	
TRIGLYCERIDES	0.3-1.5 (G/L)	23/04/91	1.72 >		2.35 >>		1.65 >	
GLOBULINS ALPHA 1	1.8-4.8 (G/L)	23/04/91	2.50		2.50		2.30	
GLOBULINS ALPHA 2	3.3-11 (G/L)	23/04/91	7.10		6.90		6.50	
GLOBULINS BETA	5.4-12.8 (G/L)	23/04/91	8.60		8.10		6.90	
GLOBULINS GAMMA	6.6-17.6 (G/L)	23/04/91	5.70 <		5.70 <		4.80 <	
TSH	0.15-3 (UU/ML)	23/04/91	0.43					
T4	9-24 (PMOL/L)	23/04/91	13.10					

1697

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/3 Patient: 68 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/01/92		10/02/92		02/03/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	13-18 (G/100ML)	23/04/91	13.40		14.30		14.20	
HT	40-50 (%)	23/04/91	39.70	<	43.10		43.70	
RBC	4.2-4.9 (10 ⁶ /MM ³)	23/04/91	4.33		4.82		4.88	
WBC	4-10 (10 ³ /MM ³)	23/04/91	6.30		6.40		7.50	
WBC: N	2-7.5 (10 ³ /MM ³)	23/04/91	3.60				4.70	
WBC: L	1.5-4 (10 ³ /MM ³)	23/04/91	1.90				2.30	
WBC: E	0.04-0.4 (10 ³ /MM ³)	23/04/91	0.20					
WBC: M	0.2-0.8 (10 ³ /MM ³)	23/04/91	0.60				0.40	
PLATELETS	150-400 (10 ³ /MM ³)	23/04/91	271.00		283.00		351.00	
NA+	135-145 (MEQ/L)	23/04/91	138.00		142.00		141.00	
K+	3.5-5 (MEQ/L)	23/04/91	3.60		4.10		4.20	
CL-	95-105 (MEQ/L)	23/04/91	103.00		101.00		102.00	
Ca++	85-105 (MG/L)	23/04/91	89.00		93.00		95.00	
PO4--	22-45 (MG/L)	23/04/91	35.00		33.00		31.00	
SGOT	8-30 (UI/L)	23/04/91	11.00		11.00		10.00	
SGPT	7-46 (UI/L)	23/04/91	17.00		16.00		13.00	
GAMMA GT	5-36 (UI/L)	23/04/91	30.00		24.00		31.00	
LDH	260-330 (UI/L)	23/04/91	147.00	<	213.00	<	182.00	
ALK. PHOSPH.	80-220 (UI/L)	23/04/91	71.00	<	93.00		99.00	
GLUCOSE	0.65-1.1 (G/L)	23/04/91	1.16	>	0.81		0.85	
UREA	0.15-0.45 (G/L)	23/04/91	0.37		0.20		0.25	
CREATININE	3-15 (MG/L)	23/04/91	11.90		11.00		11.00	
URIC ACID	25-60 (MG/L)	23/04/91	66.00	>	56.00		61.00	
TOT BILIRUBIN	1.5-12 (MG/L)	23/04/91	8.00		4.00		5.00	
DIR BILIRUBIN	0-3 (MG/L)	23/04/91	1.00		0.00		1.00	
TOT. PROTEINS	60-80 (G/L)	23/04/91	63.00		75.00		75.00	
ALBUMINE	33-50 (G/L)	23/04/91	43.00		54.00	>	47.80	
TOT. CHOLEST.	1.3-2.1 (G/L)	23/04/91	2.00		2.90	>>	2.86	
TRIGLYCERIDES	0.3-1.5 (G/L)	23/04/91	2.51	>>	2.09	>>	1.54	
GLOBULINS ALPHA 1	1.8-4.8 (G/L)	23/04/91	2.40		2.50		2.40	
GLOBULINS ALPHA 2	3.3-11 (G/L)	23/04/91	5.80		6.50		5.80	
GLOBULINS BETA	5.4-12.8 (G/L)	23/04/91	7.70		8.50		8.00	
GLOBULINS GAMMA	6.6-17.6 (G/L)	23/04/91	8.80		11.40		11.00	
TSH	0.15-3 (UU/ML)	23/04/91	3.84	>>				
T4	9-24 (PMOL/L)	23/04/91	17.30					

1698

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/3 Patient: 69 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			31/01/92		24/02/92		16/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/100ML)	23/04/91	14.60		14.50		14.40	
HT	40-50 (%)	23/04/91	45.10		44.70		46.20	
RBC	4.2-4.9 (10 ⁶ /MM ³)	23/04/91	5.24 >		5.22 >		5.35 >	
WBC	4-10 (10 ³ /MM ³)	23/04/91	9.90		9.90		8.70	
WBC: N	2-7.5 (10 ³ /MM ³)	23/04/91	5.30		5.30		4.60	
WBC: L	1.5-4 (10 ³ /MM ³)	23/04/91	3.20		3.40		2.80	
WBC: E	0.04-0.4 (10 ³ /MM ³)	23/04/91	0.70 >>		0.50 >		0.70 >>	
WBC: M	0.2-0.8 (10 ³ /MM ³)	23/04/91	0.60		0.60		0.80	
PLATELETS	150-400 (10 ³ /MM ³)	23/04/91	262.00		218.00		244.00	
HA+	135-145 (MEQ/L)	23/04/91	140.00		141.00		139.00	
E+	3.5-5 (MEQ/L)	23/04/91	4.60		4.50		4.30	
CL-	95-105 (MEQ/L)	23/04/91	103.00		106.00 >		106.00 >	
Ca++	85-105 (MG/L)	23/04/91	93.00		95.00		92.00	
PO4--	22-45 (MG/L)	23/04/91	46.00 >		41.00		45.00	
SGOT	8-30 (UI/L)	23/04/91	17.00		23.00		20.00	
SGPT	7-46 (UI/L)	23/04/91	25.00		46.00		37.00	
GAMMA GT	5-36 (UI/L)	23/04/91	52.00 >		23.00		25.00	
LDH	260-330 (UI/L)	23/04/91	186.00 <		160.00 <		140.00 <	
ALK. PHOSPH.	80-220 (UI/L)	23/04/91	129.00		127.00		128.00	
GLUCOSE	0.65-1.1 (G/L)	23/04/91	0.86		0.88		0.82	
UREA	0.15-0.45 (G/L)	23/04/91	0.31		0.34		0.30	
CREATININE	3-15 (MG/L)	23/04/91	9.00		7.00		7.00	
URIC ACID	25-60 (MG/L)	23/04/91	46.00		51.00		49.00	
TOT BILIRUBIN	1.5-12 (MG/L)	23/04/91	3.00		5.00		4.00	
DIR BILIRUBIN	0-3 (MG/L)	23/04/91	0.00		1.00		1.00	
TOT. PROTEINS	60-80 (G/L)	23/04/91	70.00		70.00		69.00	
ALBUMINE	33-50 (G/L)	23/04/91	45.00		49.00		47.00	
TOT. CHOLEST.	1.3-2.1 (G/L)	23/04/91	1.69		1.81		1.75	
TRIGLYCERIDES	0.3-1.5 (G/L)	23/04/91	1.26		0.62		1.06	
GLOBULINS ALPHA 1	1.8-4.8 (G/L)	23/04/91	2.10		3.10		3.50	
GLOBULINS ALPHA 2	3.3-11 (G/L)	23/04/91	4.80		5.70		5.20	
GLOBULINS BETA	5.4-12.8 (G/L)	23/04/91	8.10		7.10		6.60	
GLOBULINS GAMMA	6.6-17.6 (G/L)	23/04/91	8.30		10.90		11.30	
TSH	0.15-3 (UU/ML)	23/04/91	0.86					
T4	9-24 (PMOL/L)	23/04/91	19.40					

1699

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value nd laboratory not done () missing range value

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/3 Patient: 70 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/04/92		05/05/92		26/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/100ML)	23/04/91	15.60		13.30		14.70	
HT	40-50 (%)	23/04/91	45.50		39.60 <		44.00	
RBC	4.2-4.9 (10 ⁶ /MM ³)	23/04/91	4.85		4.32		4.74	
WBC	4-10 (10 ³ /MM ³)	23/04/91	5.20		7.10		4.90	
WBC: N	2-7.5 (10 ³ /MM ³)	23/04/91	3.10		3.80		2.40	
WBC: L	1.5-4 (10 ³ /MM ³)	23/04/91	1.60		1.90		2.00	
WBC: E	0.04-0.4 (10 ³ /MM ³)	23/04/91			0.30		1.40 >>	
WBC: M	0.2-0.8 (10 ³ /MM ³)	23/04/91	0.30		0.30		0.40	
PLATELETS	150-400 (10 ³ /MM ³)	23/04/91	210.00		248.00		289.00	
NA+	135-145 (MEQ/L)	23/04/91	143.00		138.00		142.00	
K+	3.5-5 (MEQ/L)	23/04/91	4.20		4.20		3.80	
CL-	95-105 (MEQ/L)	23/04/91	104.00		105.00		105.00	
Ca++	85-105 (MG/L)	23/04/91	98.00		89.00		94.00	
PO4--	22-45 (MG/L)	23/04/91	40.00		36.00		29.00	
SGOT	8-30 (UI/L)	23/04/91	20.00		14.00		15.00	
SGPT	7-46 (UI/L)	23/04/91	28.00		17.00		15.00	
GAMMA GT	5-36 (UI/L)	23/04/91	30.00		17.00			
LDH	260-390 (UI/L)	23/04/91	198.00 <		191.00 <			
ALK. PHOSPH.	80-220 (UI/L)	23/04/91	128.00		86.00		104.00	
GLUCOSE	0.65-1.1 (G/L)	23/04/91	0.78		0.79		0.73	
UREA	0.15-0.45 (G/L)	23/04/91	0.35		0.32		0.44	
CREATININE	3-15 (MG/L)	23/04/91	13.00		11.00		10.00	
URIC ACID	25-60 (MG/L)	23/04/91	64.00 >		65.00 >		61.00 >	
TOT BILIRUBIN	1.5-12 (MG/L)	23/04/91	10.00		4.00		4.00	
DIR BILIRUBIN	0-3 (MG/L)	23/04/91	1.00		1.00		1.00	
TOT. PROTEINS	60-80 (G/L)	23/04/91	78.00		65.00		74.00	
ALBUMINE	33-50 (G/L)	23/04/91	49.00		46.00		54.00 >	
TOT. CHOLEST.	1.3-2.1 (G/L)	23/04/91	2.68 >		2.03		2.40 >	
TRIGLYCERIDES	0.3-1.5 (G/L)	23/04/91	2.28 >>		0.97		0.64	
GLOBULINS ALPHA 1	1.8-4.8 (G/L)	23/04/91	2.50				2.80	
GLOBULINS ALPHA 2	3.3-11 (G/L)	23/04/91	6.10				6.10	
GLOBULINS BETA	5.4-12.8 (G/L)	23/04/91	9.60				8.00	
GLOBULINS GAMMA	6.6-17.6 (G/L)	23/04/91	11.00				9.10	
TSH	0.15-3 (UU/NL)	23/04/91	0.46					
T4	9-24 (PMOL/L)	23/04/91	27.90 >>					

1700

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** missing laboratory test value and laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/3 Patient: 71 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/04/92		06/05/92		27/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/100ML)	23/04/91	11.80		13.30		12.80	
HT	38-48 (%)	23/04/91	34.00 <		39.50		38.00	
RBC	4.2-4.9 (10 ⁶ /MM ³)	23/04/91	3.55 <<		4.11 <		3.97 <	
HBC	4-10 (10 ³ /MM ³)	23/04/91	5.40		5.10		5.90	
HBC: N	2-7.5 (10 ³ /MM ³)	23/04/91	5.30		2.40		3.20	
HBC: L	1.5-4 (10 ³ /MM ³)	23/04/91	2.00		2.00		2.40	
HBC: E	0.04-0.4 (10 ³ /MM ³)	23/04/91			0.05			
HBC: M	0.2-0.8 (10 ³ /MM ³)	23/04/91	0.10 <		0.50		0.30	
HBC: B	0.01-0.1 (10 ³ /MM ³)	23/04/91			0.05			
PLATELETS	150-400 (10 ³ /MM ³)	23/04/91	241.00		279.00		312.00	
NA+	135-145 (MEQ/L)	23/04/91	135.00		139.00		139.00	
K+	3.5-5 (MEQ/L)	23/04/91	4.30		3.80		4.20	
CL-	95-105 (MEQ/L)	23/04/91	105.00		104.00		102.00	
Ca++	85-105 (MG/L)	23/04/91	89.00		96.00		99.00	
PO4--	22-45 (MG/L)	23/04/91	32.00		41.00		34.00	
SGOT	8-30 (UI/L)	23/04/91	12.00		11.00		12.00	
SGPT	7-46 (UI/L)	23/04/91	8.00		12.00		9.00	
GAMMA GT	5-36 (UI/L)	23/04/91	10.00		9.00			
LDH	260-330 (UI/L)	23/04/91	160.00 <		201.00 <			
ALK. PHOSPH.	80-220 (UI/L)	23/04/91	65.00 <		71.00 <		84.00	
GLUCOSE	0.65-1.1 (G/L)	23/04/91	0.95		0.88		0.78	
UREA	0.15-0.45 (G/L)	23/04/91	0.16		0.22		0.23	
CREATININE	3-15 (MG/L)	23/04/91	8.00		10.00		11.00	
URIC ACID	25-60 (MG/L)	23/04/91	27.00		35.00		45.00	
TOT BILIRUBIN	1.5-12 (MG/L)	23/04/91	4.00		4.00		3.00	
DIR BILIRUBIN	0-3 (MG/L)	23/04/91	1.00		1.00		0.00	
TOT. PROTEINS	60-80 (G/L)	23/04/91	65.00		75.00		76.00	
ALBUMINE	33-50 (G/L)	23/04/91	45.00		46.30		46.00	
TOT. CHOLEST.	1.3-2.1 (G/L)	23/04/91	1.57		2.48 >		2.13 >	
TRIGLYCERIDES	0.3-1.5 (G/L)	23/04/91	0.76		0.87		0.82	
GLOBULINS ALPHA 1	1.8-4.8 (G/L)	23/04/91	2.10		3.80		3.00	
GLOBULINS ALPHA 2	3.3-11 (G/L)	23/04/91	5.60		6.00		6.90	
GLOBULINS BETA	5.4-12.8 (G/L)	23/04/91	7.10		8.00		7.80	
GLOBULINS GAMMA	6.6-17.6 (G/L)	23/04/91	8.70		10.50		11.50	
TSH	0.15-3 (UU/ML)	23/04/91	0.61					
T4	9-24 (PNOL/L)	23/04/91	16.40					

1701

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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/3 Patient: 72 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/07/92		14/08/92		04/09/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/100ML)	23/04/91	14.90		13.80		14.00	
HT	40-50 (%)	23/04/91	42.30		39.20 <		39.50 <	
RBC	4.2-4.9 (10 ⁶ /MM ³)	23/04/91	4.76		4.43		4.50	
HBC	4-10 (10 ³ /MM ³)	23/04/91	10.80 >		11.50 >		8.80	
HBC: N	2-7.5 (10 ³ /MM ³)	23/04/91			7.80 >		4.00	
HBC: L	1.5-4 (10 ³ /MM ³)	23/04/91			2.30		3.80	
HBC: E	0.04-0.4 (10 ³ /MM ³)	23/04/91			0.30		0.30	
HBC: M	0.2-0.8 (10 ³ /MM ³)	23/04/91			1.00 >		0.70	
HBC: B	0.01-0.1 (10 ³ /MM ³)	23/04/91			0.00 <			
PLATELETS	150-400 (10 ³ /MM ³)	23/04/91	310.00		291.00		307.00	
NA+	135-145 (MEQ/L)	23/04/91	137.00		139.00		135.00	
K+	3.5-5 (MEQ/L)	23/04/91	4.30		3.70			
CL-	95-105 (MEQ/L)	23/04/91	103.00		103.00		106.00 >	
Ca++	85-105 (MG/L)	23/04/91	97.00		97.00		94.00	
PO4--	22-45 (MG/L)	23/04/91	42.00		43.00			
SGOT	8-30 (UI/L)	23/04/91	20.00		14.00		13.00	
SGPT	7-46 (UI/L)	23/04/91	24.00		19.00		17.00	
GAMMA GT	5-36 (UI/L)	23/04/91	60.00 >		28.00			
LDH	260-330 (UI/L)	23/04/91	178.00 <		188.00 <			
ALK. PHOSPH.	80-220 (UI/L)	23/04/91	165.00		143.00		147.00	
GLUCOSE	0.65-1.1 (G/L)	23/04/91	0.99		0.96			
UREA	0.15-0.45 (G/L)	23/04/91	0.37		0.19		0.24	
CREATININE	3-15 (MG/L)	23/04/91	10.00		10.00		10.00	
URIC ACID	25-60 (MG/L)	23/04/91	35.00		41.00		49.00	
TOT. BILIRUBIN	1.5-12 (MG/L)	23/04/91	13.00 >		5.00		6.00	
DIR BILIRUBIN	0-3 (MG/L)	23/04/91	2.00		1.00		1.00	
TOT. PROTEINS	60-80 (G/L)	23/04/91	77.00		76.00		78.00	
ALBUMINE	33-50 (G/L)	23/04/91	48.00		44.30		49.10	
TOT. CHOLEST.	1.3-2.1 (G/L)	23/04/91	2.23 >		2.04		1.98	
TRIGLYCERIDES	0.3-1.5 (G/L)	23/04/91	1.00		1.22		0.73	
GLOBULINS ALPHA 1	1.8-4.8 (G/L)	23/04/91	3.60		3.20		2.90	
GLOBULINS ALPHA 2	3.3-11 (G/L)	23/04/91	6.40		5.50		6.00	
GLOBULINS BETA	5.4-12.8 (G/L)	23/04/91	8.30		7.80		9.00	
GLOBULINS GAMMA	6.6-17.6 (G/L)	23/04/91	11.20		7.30		11.00	
TSH	0.15-3 (UU/ML)	23/04/91	0.57					
T4	9-24 (PMOL/L)	23/04/91	19.60					

1702

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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 79 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/05/91		24/05/91		19/06/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/91	11.90	<	12.20		11.80 <	
HT	37-47 (X)	01/04/91	34.70	<	34.20	<	34.40 <	
RBC	4.2-5.4 (10 ⁶ /UL)	01/04/91	4.04	<	4.10	<	3.93 <	
WBC	4.8-10.8 (10 ³ /UL)	01/04/91	4.68	<	4.46	<	4.72 <	
WBC: N	40-74 (X)	01/04/91	43.20		41.00		54.70	
WBC: L	19-48 (X)	01/04/91	45.80		45.60		34.20	
WBC: E	0-7 (X)	01/04/91	2.60		3.20		2.40	
WBC: M	3.4-9 (X)	01/04/91	5.80		6.00		5.90	
WBC: B	0-1.5 (X)	01/04/91	0.80		1.40		0.80	
PLATELETS	130-400 (10 ³ /MM ³)	01/04/91	221.00		230.00		282.00	
NA+	136-145 (MMOL/L)	01/04/91	138.00		137.00		136.00	
K+	3.8-4.8 (MMOL/L)	01/04/91	3.84		4.08		4.08	
CL-	97-106 (MMOL/L)	01/04/91	108.00	>	102.00		102.00 <	
Ca++	2.3-2.5 (MMOL/L)	01/04/91	2.22	<	2.26	<	2.27 <	
PO4--	1-1.3 (MMOL/L)	01/04/91			1.25		1.22	
SGOT	10-30 (UI/L)	01/04/91	12.00		20.00		28.00	
SGPT	10-40 (UI/L)	01/04/91	13.00		18.00		14.00	
GAMMA GT	5-35 (UI/L)	01/04/91			9.00		7.00	
LDH	250-320 (UI/L)	01/04/91	183.00	<	188.00	<	194.00 <	
ALK. PHOSPH.	30-90 (UI/L)	01/04/91	32.00		34.00		57.00	
GLUCOSE	4-6 (MMOL/L)	01/04/91	4.80		5.00		4.70	
UREA	3.3-7 (MMOL/L)	01/04/91	6.20		4.10		5.60	
CREATININE	45-108 (UMOL/L)	01/04/91	77.00		69.00		69.00	
URIC ACID	180-350 (UMOL/L)	01/04/91	158.00	<	128.00	<	95.00 <	
TOT. BILIRUBIN	3-17 (UMOL/L)	01/04/91	22.00	>	27.00	>	15.00	
TOT. PROTEINS	65-79 (G/L)	01/04/91	67.00		73.00		78.00	
ALBUMINE	57-65 (X)	01/04/91	53.50	<	55.10	<		
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/04/91	5.10		5.58		6.26	
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/04/91	1.00		1.14		0.81	
GLOBULINS ALPHA 1	2-4 (X)	01/04/91	2.50		2.70			
GLOBULINS ALPHA 2	6-10 (X)	01/04/91	7.90		7.30			
GLOBULINS BETA	8-12 (X)	01/04/91	11.90		10.80			
GLOBULINS GAMMA	10-20 (X)	01/04/91	24.20	>	24.10	>		
TSH	0.3-3.5 (MU/L)	01/04/91	0.83					
T4	13-28 (PMOL/L)	01/04/91	19.90					

1703

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 ** missing laboratory test value and laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D
 REBONEXTINE - PROTOCOL 2012A/015
 Listing No.: 18.0
 LABORATORY DATA 9550082
 Centre: S/4 Patient: 80 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			31/08/91
			value (4)
Laboratory test	Range value	Range date	
HB	14-18 (G/DL)	01/04/91	15.10
HT	42-52 (X)	01/04/91	44.60
RBC	4.7-6.1 (10 ⁶ /UL)	01/04/91	4.92
HBC	4.8-10.8 (10 ⁹ /UL)	01/04/91	6.55
HBC: N	40-74 (X)	01/04/91	65.10
HBC: L	19-48 (X)	01/04/91	24.70
HBC: E	0-7 (X)	01/04/91	1.80
HBC: H	3.4-9 (X)	01/04/91	5.90
HBC: B	0-1.5 (X)	01/04/91	0.20
Na+	136-145 (MMOL/L)	01/04/91	141.00
K+	3.8-4.8 (MMOL/L)	01/04/91	3.70 <
CL-	97-106 (MMOL/L)	01/04/91	104.00
Ca++	2.3-2.6 (MMOL/L)	01/04/91	2.30
PO4--	1-1.3 (MMOL/L)	01/04/91	1.15
SGOT	10-30 (UI/L)	01/04/91	13.00
SGPT	10-40 (UI/L)	01/04/91	12.00
GAMMA GT	5-35 (UI/L)	01/04/91	17.00
LDH	250-320 (UI/L)	01/04/91	180.00 <
ALK. PHOSPH.	30-90 (UI/L)	01/04/91	37.00
GLUCOSE	4-6 (MMOL/L)	01/04/91	5.00
UREA	3.3-7 (MMOL/L)	01/04/91	8.60 >
CREATININE	45-108 (UMOL/L)	01/04/91	79.00
TOT. BILIRUBIN	3-17 (UMOL/L)	01/04/91	29.00 >
TOT. PROTEINS	65-79 (G/L)	01/04/91	65.00 <
ALBUMINE	37-65 (X)	01/04/91	62.40
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/04/91	7.45 >
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/04/91	1.33
GLOBULINS ALPHA 1	2-4 (X)	01/04/91	3.60
GLOBULINS ALPHA 2	6-10 (X)	01/04/91	9.20
GLOBULINS BETA	8-12 (X)	01/04/91	14.30 >
GLOBULINS GAMMA	10-20 (X)	01/04/91	10.50
TSH	0.3-3.3 (MU/L)	01/04/91	1.85
T4	13-28 (PMOL/L)	01/04/91	17.40

1704

(e) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 xx missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 81 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/05/91		04/06/91		28/06/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	10/05/91	13.50		13.70		13.00	
HT	37-47 (%)	10/05/91	39.30		40.10		37.20	
RBC	4.2-5.4 (10 ⁶ /UL)	10/05/91	4.30		4.28		4.00 <	
WBC	4.8-10.8 (10 ³ /UL)	10/05/91	5.23		6.54		6.77 >	
WBC: N	40-74 (%)	10/05/91	54.50		54.70		75.30 >	
WBC: L	19-48 (%)	10/05/91	29.60		26.40		8.10 <<	
WBC: E	0-7 (%)	10/05/91	4.90		4.60		3.00	
WBC: M	3.4-9 (%)	10/05/91	6.40		10.30 >		10.50 >	
WBC: B	0-1.5 (%)	10/05/91	0.90		1.20		0.50	
PLATELETS	130-400 (10 ³ /MM ³)	10/05/91	258.00		149.00		126.00 <	
NA+	136-145 (MMOL/L)	10/05/91	138.00		140.00		138.00	
K+	3.8-4.8 (MMOL/L)	10/05/91	3.98		3.52 <		3.35 <	
CL-	97-106 (MMOL/L)	10/05/91	102.00		105.00		104.00	
Ca++	2.3-2.5 (MMOL/L)	10/05/91	2.17 <		2.20 <		2.23 <	
PO4--	25-45 (NG/L)	10/05/91	27.00		28.00			
	1-1.3 (MMOL/L)	25/06/91					1.28	
SGOT	10-30 (UI/L)	10/05/91	14.00		12.00		14.00	
SGPT	10-40 (UI/L)	10/05/91	14.00		14.00		15.00	
GAMMA GT	5-35 (UI/L)	10/05/91	30.00		18.00		29.00	
LDH	250-320 (UI/L)	10/05/91	174.00 <		203.00 <		281.00	
ALK. PHOSPH.	30-90 (UI/L)	10/05/91	57.00		44.00		58.00	
GLUCOSE	4-6 (MMOL/L)	10/05/91	4.90		4.50		4.80	
UREA	3.3-7 (MMOL/L)	25/06/91					5.20	
CREATININE	45-108 (UMOL/L)	10/05/91	55.00		55.00		50.00	
URIC ACID	180-350 (UMOL/L)	10/05/91	121.00 <		140.00 <		130.00 <	
TOT BILIRUBIN	3-17 (UMOL/L)	10/05/91	6.00		6.00		7.00	
TOT. PROTEINS	65-79 (G/L)	10/05/91	66.00		71.00		72.00	
ALBUMINE	57-65 (%)	10/05/91	55.60 <				41.60 <	
TOT. CHOLEST.	4.4-7 (MMOL/L)	10/05/91	5.32		4.75		4.92	
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	10/05/91	0.67		1.07		1.02	
GLOBULINS ALPHA 1	2-4 (%)	10/05/91	2.90				2.90	
GLOBULINS ALPHA 2	6-10 (%)	10/05/91	7.30				8.60	
GLOBULINS BETA	8-12 (%)	10/05/91	8.30				8.90	
GLOBULINS GAMMA	10-20 (%)	10/05/91	10.60				9.70 <	
TSH	0.3-3.5 (MU/L)	10/05/91	0.70					
T4	13-28 (PMOL/L)	10/05/91	14.70					

1705

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 82 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/06/91		08/07/91		29/07/91	
			value	(⚡)	value	(⚡)	value	(⚡)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/04/91	16.40		14.00		14.20	
HT	42-52 (%)	01/04/91	45.70		45.20		39.80 <	
RBC	4.7-6.1 (10 ⁶ /UL)	01/04/91	5.48		5.11		4.73	
WBC	4.8-10.8 (10 ³ /UL)	01/04/91	6.23		5.07		5.45	
WBC: N	40-74 (%)	01/04/91	48.90		45.30		47.70	
WBC: L	19-48 (%)	01/04/91	35.10		38.00		35.80	
WBC: E	0-7 (%)	01/04/91	4.80		4.30		5.20	
WBC: M	3.4-9 (%)	01/04/91	8.60		9.40		8.00 >	
WBC: B	0-1.5 (%)	01/04/91	0.60		0.70		1.20	
PLATELETS	130-400 (10 ³ /MM ³)	01/04/91	270.00		281.00		277.00	
NA+	136-145 (MMOL/L)	01/04/91	140.00		141.00		139.00	
K+	3.8-4.8 (MMOL/L)	01/04/91	4.12		4.07		4.72	
CL-	97-106 (MMOL/L)	01/04/91	104.00		102.00		102.00	
Ca++	2.3-2.5 (MMOL/L)	01/04/91	2.32		2.34		2.25 <	
PO4--	1-1.3 (MMOL/L)	01/07/91			1.15		1.33 >	
SGOT	10-30 (UI/L)	01/04/91	15.00		18.00		21.00	
SGPT	10-40 (UI/L)	01/04/91	13.00		27.00		17.00	
GAMMA GT	5-35 (UI/L)	01/04/91	35.00		24.00		21.00	
LDH	250-320 (UI/L)	01/07/91			172.00 <			
ALK. PHOSPH.	30-90 (UI/L)	01/04/91	35.00		43.00		39.00	
GLUCOSE	4-6 (MMOL/L)	01/04/91	6.00		5.30		5.20	
UREA	3.3-7 (MMOL/L)	01/07/91			6.80		5.50	
CREATININE	45-108 (UMOL/L)	01/04/91	93.00		93.00		89.00	
URIC ACID	180-350 (UMOL/L)	01/04/91	287.00		320.00		286.00	
TOT. BILIRUBIN	3-17 (UMOL/L)	01/04/91	17.00		15.00		12.00	
TOT. PROTEINS	65-79 (G/L)	01/04/91	71.00		76.00		67.00	
ALBUMINE	57-65 (%)	01/04/91	57.40					
	37-50 (G/L)	01/07/91			44.90		40.30	
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/04/91	5.94		5.27		5.11	
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/04/91	1.29		1.38		1.39	
GLOBULINS ALPHA 1	2-4 (%)	01/04/91	2.80		1.50 <		1.60 <	
GLOBULINS ALPHA 2	6-10 (%)	01/04/91	9.30		6.00		6.90	
GLOBULINS BETA	8-12 (%)	01/04/91	14.70 >		11.10		9.80 <	
GLOBULINS GAMMA	10-20 (%)	01/04/91	15.80		12.20		8.80 <	
TSH	0.3-3.5 (MU/L)	01/04/91	0.51					
T4	13-28 (PMOL/L)	01/04/91	22.30					

1706

(⚡) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 83 Treatment: Placebo Sex: Male

			Visit number / Laboratory date
			Screen
			13/06/91
			value (c)
Laboratory test	Range value	Range date	
HB	14-18 (G/DL)	01/04/91	16.20
HT	42-52 (X)	01/04/91	46.10
RBC	4.7-6.1 (10 ⁶ /UL)	01/04/91	5.16
WBC	4.8-10.8 (10 ³ /UL)	01/04/91	6.17
WBC: N	40-74 (X)	01/04/91	53.00
WBC: L	19-48 (X)	01/04/91	36.50
WBC: E	0-7 (X)	01/04/91	2.00
WBC: M	3.4-9 (X)	01/04/91	5.30
WBC: B	0-1.5 (X)	01/04/91	0.90
PLATELETS	130-400 (10 ³ /MM ³)	01/04/91	172.00
NA+	136-145 (MMOL/L)	01/04/91	141.00
K+	3.8-4.8 (MMOL/L)	01/04/91	3.69 <
CL-	97-106 (MMOL/L)	01/04/91	107.00 >
Ca++	2.3-2.5 (MMOL/L)	01/04/91	2.50
PO4--	1-1.3 (MMOL/L)	01/04/91	1.18
SGOT	10-30 (UI/L)	01/04/91	18.00
SGPT	10-40 (UI/L)	01/04/91	21.00
GAMMA GT	5-35 (UI/L)	01/04/91	20.00
LDH	250-320 (UI/L)	01/04/91	168.00 <
ALK. PHOSPH.	30-90 (UI/L)	01/04/91	57.00
GLUCOSE	4-6 (MMOL/L)	01/04/91	5.30
UREA	3.3-7 (MMOL/L)	01/04/91	6.80
CREATININE	45-108 (UMOL/L)	01/04/91	110.00 >
URIC ACID	180-350 (UMOL/L)	01/04/91	374.00 >
TOT. BILIRUBIN	3-17 (UMOL/L)	01/04/91	6.00
TOT. PROTEINS	65-79 (G/L)	01/04/91	73.00
ALBUMINE	57-65 (X)	01/04/91	40.00 <
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/04/91	6.49
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/04/91	2.13 >
GLOBULINS ALPHA 1	2-4 (X)	01/04/91	2.30
GLOBULINS ALPHA 2	6-10 (X)	01/04/91	7.80
GLOBULINS BETA	8-12 (X)	01/04/91	10.30
GLOBULINS GAMMA	10-20 (X)	01/04/91	12.70
TSH	0.3-3.5 (MU/L)	01/04/91	1.07
T4	13-28 (PMOL/L)	01/04/91	19.50

1707

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/4 Patient: 84 Treatment: Roboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/10/91		31/10/91		12/11/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/91	13.40					
HT	37-47 (%)	01/04/91	38.90					
RBC	4.2-5.4 (10 ⁶ /UL)	01/04/91	4.19	<				
WBC	4.8-10.8 (10 ³ /UL)	01/04/91	9.22					
WBC: N	40-74 (%)	01/04/91	54.30					
WBC: L	19-48 (%)	01/04/91	37.70					
WBC: E	0-7 (%)	01/04/91	1.10					
WBC: M	3.4-9 (%)	01/04/91	4.90					
WBC: B	0-1.5 (%)	01/04/91	0.60					
PLATELETS	130-400 (10 ³ /MM3)	01/04/91	265.00					
NA+	136-145 (MMOL/L)	01/04/91	142.00		138.00	139.00		
K+	3.8-4.8 (MMOL/L)	01/04/91	3.84		4.09	3.80		
CL-	97-106 (MMOL/L)	01/04/91	105.00		101.00	101.00		
Ca++	2.3-2.5 (MMOL/L)	01/04/91	2.27	<	2.42	2.37		
PO4--	1-1.3 (MMOL/L)	01/04/91	1.27		1.25	0.96	<	
SGOT	10-30 (UI/L)	01/04/91	12.00		13.00	18.00		
SGPT	10-40 (UI/L)	01/04/91	17.00		9.00	10.00		
GAMMA GT	5-35 (UI/L)	01/04/91	52.00	>	20.00	12.00		
LDH	250-320 (UI/L)	01/04/91	155.00	<	164.00	179.00	<	
ALK. PHOSPH.	30-90 (UI/L)	01/04/91	40.00		48.00	47.00		
GLUCOSE	4-6 (MMOL/L)	01/04/91	5.60		6.20	6.90	>	
UREA	3.3-7 (MMOL/L)	01/04/91	3.30		4.80	3.00	<	
CREATININE	45-108 (UMOL/L)	01/04/91	81.00		79.00	66.00		
URIC ACID	180-350 (UMOL/L)	01/04/91			328.00	251.00		
TOT. BILIRUBIN	3-17 (UMOL/L)	01/04/91	9.00		11.00	7.00		
TOT. PROTEINS	65-79 (G/L)	01/04/91	69.00		78.00	75.00		
ALBUMINE	57-65 (%)	01/04/91	58.70		49.00	50.80	<	
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/04/91	4.47		4.80			
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/04/91	1.14		1.52			
GLOBULINS ALPHA 1	2-4 (%)	01/04/91	3.80		5.00	4.30	>	
GLOBULINS ALPHA 2	6-10 (%)	01/04/91	9.40		11.30	8.50		
GLOBULINS BETA	8-12 (%)	01/04/91	10.50		16.40	11.60		
GLOBULINS GAMMA	10-20 (%)	01/04/91	17.60		18.30	12.40		

1708

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 85 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/10/91		19/11/91		09/12/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	20/10/91	11.50	<	10.80	<	10.80	<
HT	37-47 (X)	20/10/91	35.40	<	32.80	<	31.90	<
RBC	4.2-5.4 (10 ⁶ /UL)	20/10/91	3.96	<	3.70	<	3.58	<
WBC	4.8-10.8 (10 ³ /UL)	20/10/91	3.78	<	3.59	<	3.53	<
WBC: N	40-74 (%)	20/10/91	46.90		57.00		66.10	
WBC: L	19-48 (%)	20/10/91	38.60		28.00		18.30	<
WBC: E	0-7 (%)	20/10/91	5.20		4.50		3.50	
WBC: M	3.4-9 (%)	20/10/91	6.40		8.90		7.20	
WBC: B	0-1.5 (%)	20/10/91	0.70		1.70	>	1.00	
PLATELETS	130-400 (10 ³ /MM ³)	20/10/91	287.00		197.00		249.00	
NA+	136-145 (MMOL/L)	20/10/91	143.00		139.00		140.00	
K+	3.8-4.8 (MMOL/L)	20/10/91	3.60	<	3.80		3.62	<
CL-	97-106 (MMOL/L)	20/10/91	106.00		103.00		106.00	
Ca++	2.3-2.5 (MMOL/L)	20/10/91	2.32		2.14	<	2.13	<
PO4--	1-1.3 (MMOL/L)	20/10/91	1.16		1.29		1.16	
SGOT	10-30 (UI/L)	20/10/91	8.00	<	12.00		9.00	<
SGPT	10-40 (UI/L)	20/10/91	7.00	<	10.00		12.00	
GAMMA GT	5-35 (UI/L)	20/10/91	13.00		4.00	<	8.00	
LDH	250-320 (UI/L)	20/10/91	151.00	<	178.00	<	219.00	<
ALK. PHOSPH.	30-90 (UI/L)	20/10/91	40.00		38.00		27.00	<
GLUCOSE	4-6 (MMOL/L)	20/10/91	5.09		4.10		4.70	
UREA	3.3-7 (MMOL/L)	20/10/91	4.20		4.10		4.10	
CREATININE	45-108 (UMOL/L)	20/10/91	79.00		78.00		74.00	
URIC ACID	180-350 (UMOL/L)	20/10/91	239.00		288.00		234.00	
TOT. BILIRUBIN	3-17 (UMOL/L)	20/10/91	6.00		6.00		8.00	
TOT. PROTEINS	65-79 (G/L)	20/10/91	72.00		65.00		69.00	
ALBUMINE	37-50 (G/L)	20/10/91	38.70		35.40	<		
TOT. CHOLEST.	4.4-7 (MMOL/L)	20/10/91	4.68		4.97		5.90	
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	20/10/91	0.71		0.59		0.54	<
GLOBULINS ALPHA 1	2-4 (%)	20/10/91	3.10		2.40			
GLOBULINS ALPHA 2	6-10 (%)	20/10/91	7.60		4.70	<		
GLOBULINS BETA	8-12 (%)	20/10/91	10.40		8.60			
GLOBULINS GAMMA	10-20 (%)	20/10/91	12.20		10.50			
TSH	0.3-3.5 (MU/L)	20/10/91	2.96					
T4	13-28 (PMOL/L)	20/10/91	19.10					

1709

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/4 Patient: 86 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 42	
			02/12/91		15/01/92	
			value	(#)	value	(#)
Laboratory test	Range value	Range date				
HB	14-18 (G/DL)	01/04/91	14.90		14.00	
HT	42-52 (X)	01/04/91	44.20		40.70 <	
RBC	4.7-6.1 (10 ⁶ /UL)	01/04/91	5.10		4.65 <	
WBC	4.8-10.8 (10 ³ /UL)	01/04/91	9.92		6.99	
WBC: N	40-74 (X)	01/04/91	59.30		66.40	
WBC: L	19-48 (X)	01/04/91	27.00		24.70	
WBC: E	0-7 (X)	01/04/91	4.60		0.00	
WBC: M	3.4-9 (X)	01/04/91	6.10		5.70	
WBC: B	0-1.5 (X)	01/04/91	0.60		0.50	
PLATELETS	130-400 (10 ³ /MM3)	01/04/91	165.00		185.00	
NA+	136-145 (MMOL/L)	01/04/91	140.00		139.00	
K+	3.8-4.8 (MMOL/L)	01/04/91	3.27 <		4.33	
CL-	97-106 (MMOL/L)	01/04/91	104.00		102.00	
Ca++	2.3-2.5 (MMOL/L)	01/04/91	2.36		2.30	
PO4--	1-1.3 (MMOL/L)	01/04/91	0.77 <<		0.86 <	
SGOT	10-30 (UI/L)	01/04/91	21.00		20.00	
SGPT	10-40 (UI/L)	01/04/91	27.00		36.00	
GAMMA GT	5-35 (UI/L)	01/04/91	5.00		25.00	
LDH	250-320 (UI/L)	01/04/91	220.00 <		200.00 <	
ALK. PHOSPH.	30-90 (UI/L)	01/04/91	42.00		59.00	
GLUCOSE	4-6 (MMOL/L)	01/04/91	5.60		4.60	
UREA	3.3-7 (MMOL/L)	01/04/91	4.10			
CREATININE	45-108 (UMOL/L)	01/04/91	80.00		80.00	
URIC ACID	180-350 (UMOL/L)	01/04/91	337.00		304.00	
TOT. BILIRUBIN	3-17 (UMOL/L)	01/04/91	16.00		13.00	
TOT. PROTEINS	65-79 (G/L)	01/04/91	82.00 >		79.80 >	
ALBUMINE	57-65 (X)	01/04/91	44.10 <		45.90 <	
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/04/91	5.57		5.13	
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/04/91	1.70		0.73	
GLOBULINS ALPHA 1	2-4 (X)	01/04/91	2.20		3.00	
GLOBULINS ALPHA 2	6-10 (X)	01/04/91	5.50 <		6.40	
GLOBULINS BETA	8-12 (X)	01/04/91	10.60		9.20	
GLOBULINS GAMMA	10-20 (X)	01/04/91	19.60		15.30	
TSH	0.3-3.5 (MU/L)	01/04/91	1.63			
T4	13-28 (PMOL/L)	01/04/91	20.80			

1710

(#) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/4 Patient: 87 Treatment: Placobo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/12/91		27/12/91		20/01/92	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/12/91	14.30		12.70		13.10	
HT	37-47 (X)	01/12/91	42.90		38.70		40.50	
RBC	4.2-5.4 (10 ⁶ /UL)	01/12/91	4.78		4.18 <		4.40	
HBC	4.8-10.8 (10 ³ /UL)	01/12/91	7.55		6.16		6.60	
HBC: N	40-74 (X)	01/12/91	62.70		61.30		67.10	
HBC: L	19-48 (X)	01/12/91	24.90		25.30		17.80 <	
HBC: E	0-7 (X)	01/12/91	1.80		3.90		4.20	
HBC: M	3.4-9 (X)	01/12/91	7.50		6.60		8.10	
HBC: B	0-1.5 (X)	01/12/91	0.80		0.50		0.50	
PLATELETS	130-400 (10 ³ /MM3)	01/12/91	380.00		360.00		365.00	
NA+	136-145 (MMOL/L)	01/12/91	141.00		138.00		139.00	
K+	3.8-4.8 (MMOL/L)	01/12/91	3.65 <		3.67 <		3.63 <	
CL-	97-106 (MMOL/L)	01/12/91	104.00		105.00		109.00 >	
Ca++	2.3-2.5 (MMOL/L)	01/12/91	2.47		2.33		2.49	
PO4--	1-1.3 (MMOL/L)	01/12/91	1.37 >		1.23			
SGOT	10-30 (UI/L)	01/12/91	14.00		10.00		9.00 <	
SGPT	10-40 (UI/L)	01/12/91	20.00		5.00 <		8.00 <	
GAMMA GT	5-35 (UI/L)	01/12/91	19.00		8.00		14.00	
LDH	250-320 (UI/L)	01/12/91	237.00 <		181.00 <		260.00	
ALK. PHOSPH.	30-90 (UI/L)	01/12/91	64.00		40.00		61.00	
GLUCOSE	4-6 (MMOL/L)	01/12/91	4.20		4.30		4.30	
UREA	3.3-7 (MMOL/L)	01/12/91	3.90				2.30 <	
CREATININE	45-108 (UMOL/L)	01/12/91	66.00		64.00		69.00	
URIC ACID	180-350 (UMOL/L)	01/12/91	296.00		236.00		211.00	
TOT. BILIRUBIN	3-17 (UMOL/L)	01/12/91	19.00 >		13.00		11.00	
TOT. PROTEINS	65-79 (G/L)	01/12/91	79.00		69.00		81.00 >	
ALBUMINE	37-50 (G/L)	01/12/91	39.00		37.60		39.80	
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/12/91	7.75 >		5.98		7.32 >	
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/12/91	1.07		0.90		1.02	
GLOBULINS ALPHA 1	2-4 (X)	01/12/91	3.90		3.40		4.60 >	
GLOBULINS ALPHA 2	6-10 (X)	01/12/91	7.10		6.30		8.50	
GLOBULINS BETA	8-12 (X)	01/12/91	11.80		9.10		11.00	
GLOBULINS GAMMA	10-20 (X)	01/12/91	17.00		12.50		17.00	
TSH	0.3-3.5 (MU/L)	01/12/91	1.01					
T4	13-28 (PMOL/L)	01/12/91	19.30					

1711

(ϕ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 88 Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			18/03/92		22/04/92	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	14-18 (G/DL)	01/04/91	14.40		14.20	
HT	42-52 (%)	01/04/91	40.70	<	41.60	
RBC	4.7-6.1 (10 ⁶ /UL)	01/04/91	4.92		4.98	
MBC	4.8-10.8 (10 ³ /UL)	01/04/91	4.90		3.69	
MBC: N	40-74 (%)	01/04/91	50.00		54.10	
MBC: L	19-48 (%)	01/04/91	38.00		37.40	
MBC: E	0-7 (%)	01/04/91	2.90		0.70	
MBC: M	3.4-9 (%)	01/04/91	5.60		5.00	
MBC: B	0-1.5 (%)	01/04/91	0.60		0.60	
PLATELETS	130-400 (10 ³ /MM ³)	01/04/91	269.00		277.00	
NA+	136-145 (MMOL/L)	01/04/91	138.00		141.00	
K+	3.8-4.8 (MMOL/L)	01/04/91	3.82		3.99	
CL-	97-106 (MMOL/L)	01/04/91	106.00		107.00	
Ca++	2.3-2.5 (MMOL/L)	01/04/91	2.40		2.37	
PD4--	1-1.3 (MMOL/L)	01/04/91	1.26		1.02	
SGOT	10-30 (UI/L)	01/04/91	16.00		17.00	
SGPT	10-40 (UI/L)	01/04/91	25.00		25.00	
GAMMA GT	5-35 (UI/L)	01/04/91	31.00		35.00	
LDH	250-320 (UI/L)	01/04/91	147.00	<	263.00	
ALK. PHOSPH.	30-90 (UI/L)	01/04/91	54.00		55.00	
GLUCOSE	4-6 (MMOL/L)	01/04/91	5.80		6.90	
UREA	3.3-7 (MMOL/L)	01/04/91	7.70	>	6.80	
CREATININE	45-108 (UMOL/L)	01/04/91	89.00		88.00	
URIC ACID	180-350 (UMOL/L)	01/04/91	192.00		170.00	
TOT BILIRUBIN	3-17 (UMOL/L)	01/04/91	12.00		10.00	
TOT. PROTEINS	65-79 (G/L)	01/04/91	80.10	>	83.00	
ALBUMINE	57-65 (%)	01/04/91	47.00	<	47.20	
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/04/91	7.27	>	7.69	
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/04/91	1.34		0.89	
GLOBULINS ALPHA 1	2-4 (%)	01/04/91	2.00		2.40	
GLOBULINS ALPHA 2	6-10 (%)	01/04/91	5.90	<	7.40	
GLOBULINS BETA	8-12 (%)	01/04/91	11.50		12.10	
GLOBULINS GAMMA	10-20 (%)	01/04/91	13.70		13.90	
TSH	0.3-3.5 (MU/L)	01/04/91	0.66			
T4	13-28 (PMOL/L)	01/04/91	16.80			

1712

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 89 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/03/92		15/04/92		12/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/91	14.00		14.00		13.50	
HT	37-47 (%)	01/04/91	41.90		43.10		41.30	
RBC	4.2-5.4 (10 ⁶ /UL)	01/04/91	4.73		4.72		4.55	
WBC	4.8-10.8 (10 ³ /UL)	01/04/91	5.00		6.40		3.75 <	
WBC: N	40-74 (%)	01/04/91	47.00		36.00 <		39.50 <	
WBC: L	19-48 (%)	01/04/91	32.20		53.00 >		42.80	
WBC: E	0-7 (%)	01/04/91	4.20		6.00		4.70	
WBC: H	3.4-9 (%)	01/04/91	11.90 >>		5.00		8.50	
WBC: B	0-1.5 (%)	01/04/91	0.90		0.00		0.60	
PLATELETS	130-400 (10 ³ /MM ³)	01/04/91	219.00				123.00 <	
NA+	136-145 (MMOL/L)	01/04/91	140.00		139.00		142.00	
K+	3.8-4.8 (MMOL/L)	01/04/91	3.60 <		3.90		4.27	
CL-	97-106 (MMOL/L)	01/04/91	109.00 >		104.00		109.00 >	
Ca++	2.3-2.5 (MMOL/L)	01/04/91	2.30		2.55 >		2.38	
PO4--	1-1.3 (MMOL/L)	01/04/91	0.99 <		1.43 >			
SGOT	10-30 (UI/L)	01/04/91	9.00 <		13.00		11.00	
SGPT	10-40 (UI/L)	01/04/91	7.00 <		7.00 <		8.00 <	
GAMMA GT	5-35 (UI/L)	01/04/91	11.00		10.00		15.00	
LDH	250-320 (UI/L)	01/04/91	190.00 <		215.00 <			
ALK. PHOSPH.	30-90 (UI/L)	01/04/91	37.00		21.00 <		24.00 <	
GLUCOSE	4-6 (MMOL/L)	01/04/91	5.00		5.05		4.80	
UREA	3.3-7 (MMOL/L)	01/04/91	2.60 <		3.48		3.00 <	
CREATININE	45-108 (UMOL/L)	01/04/91	59.00		61.00		53.00	
URIC ACID	180-350 (UMOL/L)	01/04/91			124.00 <		131.00 <	
TOT. BILIRUBIN	3-17 (UMOL/L)	01/04/91	12.00		7.00		8.00	
TOT. PROTEINS	65-79 (G/L)	01/04/91	78.00				73.00	
ALBUMINE	57-65 (%)	01/04/91	58.30		46.40 <		42.20 <	
TOT. CHOLEST.	4.4-7 (MMOL/L)	01/04/91	5.60		5.57		5.59	
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	01/04/91	1.28		0.68		0.80	
GLOBULINS ALPHA 1	2-4 (%)	01/04/91	3.00				2.10	
GLOBULINS ALPHA 2	6-10 (%)	01/04/91	8.00				5.30 <	
GLOBULINS BETA	8-12 (%)	01/04/91	11.50				8.60	
GLOBULINS GAMMA	10-20 (%)	01/04/91	19.20				14.30	
TSH	0.3-3.5 (MU/L)	01/04/91	1.27					
T4	13-28 (PMOL/L)	01/04/91	13.70					

1713

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 90 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/04/92		19/05/92		23/06/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	20/04/92	15.80		16.40		16.10	
HT	42-52 (X)	20/04/92	46.80		48.70		47.80	
RBC	4.7-6.1 (10 ⁶ /UL)	20/04/92	5.25		5.41		5.22	
WBC	4.8-10.8 (10 ³ /UL)	20/04/92	5.82		5.68		6.56	
WBC: N	40-74 (%)	20/04/92	56.90		59.90		59.20	
WBC: L	19-48 (%)	20/04/92	31.00		30.10		27.80	
WBC: E	0-7 (%)	20/04/92	3.80		1.90		2.70	
WBC: M	3.4-9 (%)	20/04/92	6.20		6.00		7.20	
WBC: B	0-1.5 (%)	20/04/92	0.60		0.40		0.90	
PLATELETS	130-400 (10 ³ /MM3)	20/04/92	285.00		288.00		292.00	
NA+	136-145 (MMOL/L)	20/04/92	140.00		142.00		140.00	
K+	3.8-4.8 (MMOL/L)	20/04/92	4.33		4.49		3.82	
CL-	97-106 (MMOL/L)	20/04/92	107.00 >		109.00 >		107.00 >	
Ca++	2.3-2.5 (MMOL/L)	20/04/92	2.45		2.52 >		2.41	
PO4--	1-1.3 (MMOL/L)	20/04/92	1.02		0.80 <<		0.79 <<	
SGOT	10-30 (UI/L)	20/04/92	29.00		13.00		13.00	
SGPT	10-40 (UI/L)	20/04/92	23.00		20.00		12.00	
GAMMA GT	5-35 (UI/L)	20/04/92	10.00		19.00		20.00	
LDH	250-320 (UI/L)	20/04/92	286.00				296.00	
ALK. PHOSPH.	30-90 (UI/L)	20/04/92	53.00		46.00		48.00	
GLUCOSE	4-6 (MMOL/L)	20/04/92	5.40		5.60		5.20	
UREA	3.3-7 (MMOL/L)	20/04/92	5.40		5.30			
CREATININE	45-108 (UMOL/L)	20/04/92	73.00		75.00		83.00	
URIC ACID	180-350 (UMOL/L)	20/04/92	287.00		257.00		328.00	
TOT. BILIRUBIN	3-17 (UMOL/L)	20/04/92	10.00		9.00		9.00	
TOT. PROTEINS	65-79 (G/L)	20/04/92	74.00		78.00		76.00	
ALBUMINE	37-50 (G/L)	20/04/92	38.40		43.00		41.00	
TOT. CHOLEST.	4.4-7 (MMOL/L)	20/04/92	7.24 >		6.72			
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	20/04/92	0.95		1.23		1.02	
GLOBULINS ALPHA 1	2-4 (%)	20/04/92	2.70		2.50		2.40	
GLOBULINS ALPHA 2	6-10 (%)	20/04/92	7.30		6.60		6.30	
GLOBULINS BETA	8-12 (%)	20/04/92	10.80		10.50		10.10	
GLOBULINS GAMMA	10-20 (%)	20/04/92	14.80		15.50		16.10	
TSH	0.3-3.5 (MU/L)	20/04/92	1.46					
T4	13-28 (PMOL/L)	20/04/92	18.90					

1714

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 457 Treatment: Placebo Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			18/05/92	10/06/92
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	10/05/92	13.10	13.20
HT	37-47 (X)	10/05/92	39.80	40.70
RBC	4.2-5.4 (10 ⁶ /UL)	10/05/92	4.52	4.86
WBC	4.8-10.8 (10 ³ /UL)	10/05/92	4.09 <	5.07
WBC: N	40-74 (X)	10/05/92	51.00	40.10
WBC: L	19-48 (X)	10/05/92	37.00	46.50
WBC: E	0-7 (X)	10/05/92	3.70	0.21
WBC: M	3.4-9 (X)	10/05/92	5.70	6.20
WBC: B	0-1.5 (X)	10/05/92	0.80	0.90
PLATELETS	130-400 (10 ³ /MM ³)	10/05/92	243.00	214.00
NA+	136-145 (MMOL/L)	10/05/92	143.00	140.00
K+	3.8-4.8 (MMOL/L)	10/05/92	3.88	4.14
CL-	97-106 (MMOL/L)	10/05/92	110.00 >	102.00
Ca++	2.3-2.5 (MMOL/L)	10/05/92	2.37	2.31
PO4--	25-45 (MG/L)	10/05/92	29.00	30.00
SGOT	10-30 (UI/L)	10/05/92	16.00	10.00
SGPT	10-40 (UI/L)	10/05/92	13.00	22.00
GAMMA GT	5-35 (UI/L)	10/05/92	19.00	17.00
LDH	250-320 (UI/L)	10/05/92	184.00 <	167.00 <
ALK. PHOSPH.	30-90 (UI/L)	10/05/92	48.00	62.00
GLUCOSE	4-6 (MMOL/L)	10/05/92	5.00	4.60
UREA	3.3-7 (MMOL/L)	10/05/92	5.60	5.30
CREATININE	45-108 (UMOL/L)	10/05/92	73.00	68.00
URIC ACID	180-350 (UMOL/L)	10/05/92	321.00	320.00
TOT BILIRUBIN	3-17 (UMOL/L)	10/05/92	12.00	7.00
TOT. PROTEINS	65-79 (G/L)	10/05/92	67.00	65.00
ALBUMINE	37-50 (G/L)	10/05/92	38.70	35.30 <
TOT. CHOLEST.	4.4-7 (MMOL/L)	10/05/92	6.48	5.01
TRIGLYCERIDES	0.5-1.5 (G/L)	10/05/92	1.64 >	2.04 >>
GLOBULINS ALPHA 1	1-3 (G/L)	10/05/92	1.70	2.20
GLOBULINS ALPHA 2	4-7 (G/L)	10/05/92	6.10	5.90
GLOBULINS BETA	5-8 (G/L)	10/05/92	9.70 >	10.30 >
GLOBULINS GAMMA	8-12 (G/L)	10/05/92	10.60	11.10
TSH	0.3-3.5 (MU/L)	10/05/92	0.74	
T4	13-28 (PMOL/L)	10/05/92	13.60	

1715

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 458 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	
			18/05/92	
			value	(c)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	10/05/92	14.60	
HT	37-47 (%)	10/05/92	43.20	
NBC	4.8-10.8 (10-3/UL)	10/05/92	6.30	
NBC: N	4800-10800 (/MM3)	10/05/92	2961.00	<<
NBC: L	2000-7500 (/MM3)	10/05/92	2961.00	
NBC: E	40-700 (/MM3)	10/05/92	63.00	
NBC: M	200-1000 (/MM3)	10/05/92	315.00	
NBC: B	10-200 (/MM3)	10/05/92	0.00	<
PLATELETS	130-400 (10-3/MM3)	10/05/92	245.00	
NA+	136-145 (MMOL/L)	10/05/92	139.00	
K+	3.8-4.8 (MMOL/L)	10/05/92	3.80	
CL-	97-106 (MMOL/L)	10/05/92	110.00	>
Ca++	2.3-2.5 (MMOL/L)	10/05/92	2.38	
PO4--	25-45 (MG/L)	10/05/92	29.00	
SGOT	10-30 (UI/L)	10/05/92	11.00	
SGPT	10-40 (UI/L)	10/05/92	14.00	
GAMMA GT	5-35 (UI/L)	10/05/92	20.00	
LDH	250-320 (UI/L)	10/05/92	180.00	<
ALK. PHOSPH.	30-90 (UI/L)	10/05/92	111.00	>
GLUCOSE	0.6-1.1 (G/L)	10/05/92	1.04	
UREA	3.3-7 (MMOL/L)	10/05/92	0.35	<
CREATININE	45-108 (UMOL/L)	10/05/92	65.00	
URIC ACID	180-350 (UMOL/L)	10/05/92	291.50	
TOT BILIRUBIN	3-17 (UMOL/L)	10/05/92	10.00	
TOT. PROTEINS	65-79 (G/L)	10/05/92	69.00	
ALBUMINE	37-50 (G/L)	10/05/92	35.00	<
TOT. CHOLEST.	1.2-2.2 (G/L)	10/05/92	2.27	>
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	10/05/92	0.92	
GLOBULINS ALPHA 1	2-4 (%)	10/05/92	2.30	
GLOBULINS ALPHA 2	6-10 (%)	10/05/92	14.60	>>
GLOBULINS BETA	8-12 (%)	10/05/92	12.80	>
GLOBULINS GAMMA	10-20 (%)	10/05/92	18.50	
TSH	0.3-3.5 (MU/L)	10/05/92	3.04	
T4	13-28 (PMOL/L)	10/05/92	13.40	

1716

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 459 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			29/05/92		23/06/92		15/07/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	20/05/92	15.10		13.60		14.70	
HT	97-47 (X)	20/05/92	45.40		42.00		42.70	
RBC	4.2-5.4 (10 ⁶ /UL)	20/05/92	4.98		5.05		4.91	
WBC	4.8-10.8 (10 ³ /UL)	20/05/92	6.49		6.15		6.50	
WBC: N	40-74 (X)	20/05/92	54.80		50.40		56.80	
WBC: L	19-48 (X)	20/05/92	31.10		36.90		30.20	
WBC: E	0-7 (X)	20/05/92	1.50		3.10		2.00	
WBC: M	3.4-9 (X)	20/05/92	9.50	>	6.50		10.00	
WBC: B	0-1.5 (X)	20/05/92	1.00		0.40		1.00	
PLATELETS	130-400 (10 ³ /MM ³)	20/05/92	242.00		230.00		241.00	
NA+	136-145 (MMOL/L)	20/05/92	141.00		141.00		140.00	
K+	3.8-4.8 (MMOL/L)	20/05/92	4.90	>	4.49		4.80	
CL-	97-106 (MMOL/L)	20/05/92	105.00		104.00		104.00	
Ca++	90-105 (MG/L)	20/05/92	96.00				95.00	
	2.3-2.5 (MMOL/L)	20/06/92			2.39			
PO4--	25-45 (MG/L)	20/05/92	42.00				41.00	
SGOT	10-30 (UI/L)	20/05/92	15.00		13.00		15.00	
SGPT	10-40 (UI/L)	20/05/92	14.00		20.00		14.00	
GAMMA GT	5-35 (UI/L)	20/05/92	36.00	>	32.00		45.00	
LDH	250-320 (UI/L)	20/05/92	250.00		222.00	<	270.00	
ALK. PHOSPH.	30-90 (UI/L)	20/05/92	30.00		67.00		32.00	
GLUCOSE	0.6-1.1 (G/L)	20/05/92	0.94				0.98	
	4-6 (MMOL/L)	20/06/92			5.50			
UREA	3.3-7 (MMOL/L)	20/05/92	5.82		5.90			
CREATININE	45-108 (UMOL/L)	20/05/92	64.00		88.00		65.00	
URIC ACID	25-65 (MG/L)	20/05/92	36.00				38.00	
	180-350 (UMOL/L)	20/06/92			301.00			
TOT. BILIRUBIN	3-17 (UMOL/L)	20/05/92	5.70		8.00		5.00	
TOT. PROTEINS	65-79 (G/L)	20/05/92	67.00		71.00		68.00	
ALBUMINE	37-50 (G/L)	20/05/92	42.54					
	57-65 (X)	10/07/92					43.20	
TOT. CHOLEST.	1.2-2.2 (G/L)	20/05/92	2.44	>			2.20	
	4.4-7 (MMOL/L)	20/06/92			5.22			
TRIGLYCERIDES	0.85-1.7 (MMOL/L)	20/05/92	0.64		1.30		0.50	
GLOBULINS ALPHA 1	1-3 (G/L)	20/05/92	2.25					
	2-4 (X)	10/07/92					3.40	
GLOBULINS ALPHA 2	4-7 (G/L)	20/05/92	5.20					
	6-10 (X)	10/07/92					7.80	
GLOBULINS BETA	5-8 (G/L)	20/05/92	7.19					
	8-12 (X)	10/07/92					10.70	
GLOBULINS GAMMA	8-12 (G/L)	20/05/92	9.82					
	10-20 (X)	10/07/92					14.70	
TSH	0.3-3.5 (MU/L)	20/05/92	2.50					
T4	13-28 (PMOL/L)	20/05/92	14.20					

1717

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 460 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date
			Screen
			17/08/92
			value (φ)
Laboratory test	Range value	Range date	
HB	14-18 (G/DL)	10/08/92	15.90
HT	42-52 (%)	10/08/92	47.40
RBC	4.7-6.1 (10 ⁶ /UL)	10/08/92	5.34
WBC	4.8-10.8 (10 ³ /UL)	10/08/92	6.08
WBC: N	40-74 (%)	10/08/92	55.00
WBC: L	19-48 (%)	10/08/92	33.60
WBC: E	0-7 (%)	10/08/92	2.30
WBC: M	3.4-9 (%)	10/08/92	6.60
WBC: B	0-1.5 (%)	10/08/92	0.70
PLATELETS	130-400 (10 ³ /MM ³)	10/08/92	161.00
NA+	136-145 (MMOL/L)	10/08/92	140.00
K+	3.8-4.8 (MMOL/L)	10/08/92	3.70 <
CL-	97-106 (MMOL/L)	10/08/92	102.00
Ca++	2.3-2.5 (MMOL/L)	10/08/92	2.39
PO4--	1-1.3 (MMOL/L)	10/08/92	1.24
SGOT	10-30 (UI/L)	10/08/92	11.00
SGPT	10-40 (UI/L)	10/08/92	15.00
GAMMA GT	5-35 (UI/L)	10/08/92	2.00 <
LDH	250-320 (UI/L)	10/08/92	239.00 <
ALK. PHOSPH.	30-90 (UI/L)	10/08/92	53.00
GLUCOSE	4-6 (MMOL/L)	10/08/92	4.50
UREA	3.3-7 (MMOL/L)	10/08/92	5.70
CREATININE	45-108 (UMOL/L)	10/08/92	105.00
URIC ACID	180-350 (UMOL/L)	10/08/92	354.00 >
TOT BILIRUBIN	3-17 (UMOL/L)	10/08/92	11.00
TOT. PROTEINS	65-79 (G/L)	10/08/92	69.00
ALBUMINE	37-50 (G/L)	10/08/92	39.90
TOT. CHOLEST.	4.4-7 (MMOL/L)	10/08/92	5.23
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	10/08/92	1.60
GLOBULINS ALPHA 1	2-4 (%)	10/08/92	2.70
GLOBULINS ALPHA 2	6-10 (%)	10/08/92	6.80
GLOBULINS BETA	8-12 (%)	10/08/92	8.90
GLOBULINS GAMMA	10-20 (%)	10/08/92	10.90
TSH	0.3-3.5 (MU/L)	10/08/92	0.97
T4	13-28 (PMOL/L)	10/08/92	15.20

1718

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 3/4 Patient: 461 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			15/09/92
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	10/09/92	15.20
HT	37-47 (%)	10/09/92	44.00
RBC	4.2-5.4 (10 ⁶ /UL)	10/09/92	4.97
WBC	4.8-10.8 (10 ³ /UL)	10/09/92	6.00
WBC: N	2-7.5 (10 ³ /MM3)	10/09/92	4.02
WBC: L	1.5-4 (10 ³ /MM3)	10/09/92	1.68
WBC: E	0.04-0.7 (10 ³ /MM3)	10/09/92	0.70
WBC: M	0.2-1 (10 ³ /MM3)	10/09/92	0.30
WBC: B	0.01-0.2 (10 ³ /MM3)	10/09/92	0.20
PLATELETS	130-400 (10 ³ /MM3)	10/09/92	248.00
NA+	136-145 (MMOL/L)	10/09/92	139.00
K+	3.8-4.8 (MMOL/L)	10/09/92	4.30
CL-	97-106 (MMOL/L)	10/09/92	102.00
Ca++	2.3-2.5 (MMOL/L)	10/09/92	2.41
PO4--	1-1.3 (MMOL/L)	10/09/92	1.21
SGOT	10-30 (UI/L)	10/09/92	10.00
SGPT	10-40 (UI/L)	10/09/92	5.00 <
GAMMA GT	5-35 (UI/L)	10/09/92	12.00
LDH	250-320 (UI/L)	10/09/92	239.00 <
ALK. PHOSPH.	30-90 (UI/L)	10/09/92	65.00
GLUCOSE	4-6 (MMOL/L)	10/09/92	4.40
UREA	3.3-7 (MMOL/L)	10/09/92	3.80
CREATININE	45-108 (UMOL/L)	10/09/92	72.00
URIC ACID	180-350 (UMOL/L)	10/09/92	259.00
TOT BILIRUBIN	3-17 (UMOL/L)	10/09/92	5.00
TOT. PROTEINS	65-79 (G/L)	10/09/92	72.00
ALBUMINE	57-65 (%)	10/09/92	45.79 <
TOT. CHOLEST.	4.4-7 (MMOL/L)	10/09/92	5.96
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	10/09/92	2.62 >>
GLOBULINS ALPHA 1	2-4 (%)	10/09/92	2.38
GLOBULINS ALPHA 2	6-10 (%)	10/09/92	5.90 <
GLOBULINS BETA	8-12 (%)	10/09/92	7.78 <
GLOBULINS GAMMA	10-20 (%)	10/09/92	10.15
TSH	0.3-3.5 (MU/L)	10/09/92	2.62
T4	13-28 (PMOL/L)	10/09/92	14.90

1719

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBONETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 3/4 Patient: 462 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			29/09/92
			value (°)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	20/09/92	14.30
HT	37-47 (%)	20/09/92	40.60
RBC	4.2-5.4 (10 ⁶ /UL)	20/09/92	4.70
WBC	4.8-10.8 (10 ³ /UL)	20/09/92	8.70
WBC: N	2-7.5 (10 ³ /MM ³)	20/09/92	6.18
WBC: L	1.5-4 (10 ³ /MM ³)	20/09/92	2.18
WBC: E	0.04-0.7 (10 ³ /MM ³)	20/09/92	0.70
WBC: M	0.2-1 (10 ³ /MM ³)	20/09/92	0.35
WBC: B	0.01-0.2 (10 ³ /MM ³)	20/09/92	0.20
PLATELETS	130-400 (10 ³ /MM ³)	20/09/92	298.00
NA+	136-145 (MMOL/L)	20/09/92	140.00
K+	3.8-4.8 (MMOL/L)	20/09/92	3.90
CL-	97-106 (MMOL/L)	20/09/92	106.00
Ca++	2.3-2.5 (MMOL/L)	20/09/92	2.32
PO4--	1-1.3 (MMOL/L)	20/09/92	1.03
SGOT	10-30 (UI/L)	20/09/92	11.00
SGPT	10-40 (UI/L)	20/09/92	8.00 <
GAMMA GT	5-35 (UI/L)	20/09/92	28.00
LDH	250-320 (UI/L)	20/09/92	226.00 <
ALK. PHOSPH.	30-90 (UI/L)	20/09/92	42.00
GLUCOSE	4-6 (MMOL/L)	20/09/92	4.80
UREA	3.3-7 (MMOL/L)	20/09/92	2.30 <
CREATININE	45-108 (UMOL/L)	20/09/92	76.00
URIC ACID	180-350 (UMOL/L)	20/09/92	243.00
TOT BILIRUBIN	3-17 (UMOL/L)	20/09/92	7.00
TOT. PROTEINS	65-79 (G/L)	20/09/92	70.00
ALBUMINE	57-65 (%)	20/09/92	45.22 <
TOT. CHOLEST.	4.4-7 (MMOL/L)	20/09/92	5.36
TRIGLYCERIDES	0.55-1.7 (MMOL/L)	20/09/92	0.74
GLOBULINS ALPHA 1	2-4 (%)	20/09/92	2.24
GLOBULINS ALPHA 2	6-10 (%)	20/09/92	5.53 <
GLOBULINS BETA	8-12 (%)	20/09/92	6.93 <
GLOBULINS GAMMA	10-20 (%)	20/09/92	10.08

1720

(°) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/1 Patient: 91 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			17/10/91
			value (€)
Laboratory test	Range value	Range date	
NA+	135-145 (MEQ/L)	01/10/91	139.00
K+	3.6-5.3 (MEQ/L)	01/10/91	3.80
CL-	95-105 (MEQ/L)	01/10/91	108.00 >
Ca++	90-105 (MG/L)	01/10/91	92.00
PO4--	28-45 (MG/L)	01/10/91	38.00
SGOT	6-25 (U/L)	01/10/91	8.00
SGPT	7-28 (U/L)	01/10/91	14.00
GAMMA GT	6-26 (U/L)	01/10/91	21.00
LDH	120-280 (U/L)	01/10/91	237.00
ALK. PHOSPH.	30-90 (UI/L)	01/10/91	94.00 >
GLUCOSE	0.75-1.05 (G/L)	01/10/91	0.99
UREA	0.19-0.42 (G/L)	01/10/91	0.25
CREATININE	0.006-0.011 (G/L)	01/10/91	0.01
URIC ACID	0.03-0.06 (G/L)	01/10/91	0.04
TOT BILIRUBIN	2-10 (MG/L)	01/10/91	4.00
TOT. PROTEINS	60-78 (G/L)	01/10/91	69.00
ALBUMINE	57-61 (%)	01/10/91	56.70 <
TOT. CHOLEST.	1.3-2 (G/L)	01/10/91	2.18 >
TRIGLYCERIDES	0.45-1.2 (G/L)	01/10/91	2.04 >>
GLOBULINS ALPHA 1	3-5.5 (%)	01/10/91	5.30
GLOBULINS ALPHA 2	7-9.5 (%)	01/10/91	11.10 >
GLOBULINS BETA	10-14 (%)	01/10/91	14.10 >
GLOBULINS GAMMA	14-17 (%)	01/10/91	12.80 <
TSH	0.15-3.5 (UU/ML)	01/10/91	0.92
T4	4-12 (NG/DL)	01/10/91	11.20

1721

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 92 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/08/91		28/08/91		18/09/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	02/08/91	11.80	<	12.50		13.20	
HT	35-47 (%)	02/08/91	35.70		36.90		38.90	
RBC	4-5.2 (10 ⁶ /UL)	02/08/91	4.26		4.34		4.59	
WBC	4000-9000 (/UL)	02/08/91	4900.00		6100.00		7100.00	
WBC: N	1500-7000 (/MM3)	02/08/91	2793.00					
	50-70 (%)	27/08/91			61.00		51.00	
WBC: L	800-4500 (/MM3)	02/08/91	1519.00					
	20-45 (%)	27/08/91			30.00		36.00	
WBC: E	0-400 (/MM3)	02/08/91	147.00					
	1-4 (%)	27/08/91			1.00		2.00	
WBC: M	200-800 (/MM3)	02/08/91	392.00					
	3-8 (%)	27/08/91			6.00		10.00	>
WBC: B	0-100 (/MM3)	02/08/91	49.00					
	0-1 (%)	27/08/91			2.00	>>	1.00	
PLATELETS	150000-400000 (/UL)	02/08/91	295000		308000		490000	>
NA+	135-145 (MEQ/L)	02/08/91	142.00		142.00		141.00	
K+	3.6-5.3 (MEQ/L)	02/08/91	3.70		3.50	<	2.30	<<
CL-	95-105 (MEQ/L)	02/08/91	103.00		101.00		99.00	
Ca++	90-105 (MG/L)	02/08/91	91.00		92.00		95.00	
PO4--	28-45 (MG/L)	02/08/91	32.00		34.00		34.00	
SGOT	6-25 (U/L)	02/08/91	12.00		12.00		29.00	>
SGPT	7-28 (U/L)	02/08/91	9.00		10.00		59.00	>>
GAMMA GT	6-26 (U/L)	02/08/91	8.00		9.00		13.00	
LDH	120-280 (U/L)	02/08/91	187.00		189.00		223.00	
ALK. PHOSPH.	30-90 (UI/L)	02/08/91	29.00	<	32.00		41.00	
GLUCOSE	0.75-1.05 (G/L)	02/08/91	0.83		0.69	<	0.86	
UREA	0.19-0.42 (G/L)	02/08/91	0.17	<	0.28		0.34	
CREATININE	0.006-0.011 (G/L)	02/08/91	0.01		0.01		0.01	
URIC ACID	0.03-0.06 (G/L)	02/08/91	0.06		0.08	>>	0.09	>>
TOT BILIRUBIN	2-10 (MG/L)	02/08/91	17.00	>	23.00	>>	9.00	
TOT. PROTEINS	60-78 (G/L)	02/08/91	67.10		68.80		69.50	
ALBUMINE	57-61 (G/L)	02/08/91	65.00	>	62.00	>	65.00	>
TOT. CHOLEST.	1.3-2 (G/L)	02/08/91	1.90		1.96		1.92	
TRIGLYCERIDES	0.45-1.2 (G/L)	02/08/91	0.68		0.83		0.81	
GLOBULINS ALPHA 1	3-5.5 (%)	02/08/91	3.50		4.00		3.50	
GLOBULINS ALPHA 2	7-9.5 (%)	02/08/91	8.00		8.50		8.50	
GLOBULINS BETA	10-14 (%)	02/08/91	12.00		12.50		12.50	
GLOBULINS GAMMA	14-17 (%)	02/08/91	11.50	<	13.00	<	10.50	<
TSH	0.15-3.5 (UU/ML)	02/08/91	0.84					
T4	45-120 (NG/ML)	02/08/91	64.10					

1722

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 93 Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			29/06/91		24/07/91	
			value	(*)	value	(*)
Laboratory test	Range value	Range date				
HB	13-18 (G/DL)	01/06/91	15.40		15.10	
HT	42-52 (%)	01/06/91	44.40		44.30	
RBC	4.5-5.8 (10 ⁶ /UL)	01/06/91	4.69		4.69	
WBC	4000-9000 (/UL)	01/06/91	4200.00		4400.00	
WBC: N	45-74 (%)	01/06/91	42.00	<	30.00	<<
WBC: L	16-45 (%)	01/06/91	46.00	>	58.00	>
WBC: E	0-7 (%)	01/06/91	2.00		2.00	
WBC: M	4-10 (%)	01/06/91	9.00		10.00	
WBC: B	0-2 (%)	01/06/91	1.00		0.00	
PLATELETS	150000-400000 (/UL)	01/06/91	302000		289000	
NA+	135-145 (MEQ/L)	01/06/91	141.00		139.00	
K+	3.6-5.3 (MEQ/L)	01/06/91	4.20		4.40	
CL-	95-105 (MEQ/L)	01/06/91	100.00		97.00	
Ca++	90-105 (MG/L)	01/06/91	91.00		91.00	
PO4--	28-45 (MG/L)	01/06/91	36.00		40.00	
SGOT	7-30 (U/L)	01/06/91	10.00		14.00	
SGPT	9-33 (U/L)	01/06/91	16.00		10.00	
GAMMA GT	8-35 (U/L)	01/06/91	15.00		12.00	
LDH	120-280 (U/L)	01/06/91	192.00		185.00	
ALK. PHOSPH.	30-90 (UI/L)	01/06/91	52.00		54.00	
GLUCOSE	0.75-1.05 (G/L)	01/06/91	0.75		0.92	
UREA	0.19-0.42 (G/L)	01/06/91	0.38		0.37	
CREATININE	0.007-0.014 (G/L)	01/06/91	0.01		0.01	
URIC ACID	0.03-0.06 (G/L)	01/06/91	0.06	>	0.05	
TOT BILIRUBIN	2-10 (MG/L)	01/06/91	9.00		6.00	
TOT. PROTEINS	60-78 (G/L)	01/06/91	73.40		68.10	
ALBUMINE	57-61 (%)	01/06/91	63.00	>	61.50	>
TOT. CHOLEST.	1.3-1.7 (G/L)	01/06/91	1.71	>	1.65	
TRIGLYCERIDES	0.45-1.2 (G/L)	01/06/91	0.38	<	0.74	
GLOBULINS ALPHA 1	3-5.5 (%)	01/06/91	3.00		3.00	
GLOBULINS ALPHA 2	7-9.5 (%)	01/06/91	8.00		8.00	
GLOBULINS BETA	10-14 (%)	01/06/91	11.00		11.00	
GLOBULINS GAMMA	14-17 (%)	01/06/91	15.00		16.50	
TSH	0.15-3.5 (UU/ML)	01/06/91	1.08			
T4	45-120 (NG/ML)	01/06/91	57.60			

1723

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done (*) missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 94 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			29/06/91		24/07/91		27/08/91	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	14.10		14.60		14.70	
HT	42-52 (%)	01/06/91	41.80 <		44.10		44.00	
RBC	4.5-5.8 (10 ⁶ /UL)	01/06/91	4.47 <		4.72		4.62	
HBC	4000-9000 (/UL)	01/06/91	9000.00		8800.00		10000.00 >	
HBC: N	45-74 (%)	01/06/91	33.00 <		39.00 <		41.00 <	
HBC: L	16-45 (%)	01/06/91	36.00		43.00		38.00	
HBC: E	0-7 (%)	01/06/91	22.00 >>		11.00 >>		15.00 >>	
HBC: M	4-10 (%)	01/06/91	8.00		7.00		6.00	
HBC: B	0-2 (%)	01/06/91	1.00		0.00		0.00	
PLATELETS	150000-400000 (/UL)	01/06/91	293000		310000		321000	
NA+	135-145 (MEQ/L)	01/06/91	142.00		140.00		143.00	
K+	3.6-5.3 (MEQ/L)	01/06/91	3.90		4.60		4.70	
CL-	95-105 (MEQ/L)	01/06/91	104.00		99.00		103.00	
Ca++	90-105 (MG/L)	01/06/91	93.00		98.00		99.00	
PO4--	28-45 (MG/L)	01/06/91	29.00		31.00		28.00	
SGOT	7-30 (U/L)	01/06/91	14.00		11.00		11.00	
SGPT	9-33 (U/L)	01/06/91	15.00		18.00		9.00	
GAMMA GT	8-35 (U/L)	01/06/91	10.00		13.00		13.00	
LDH	120-280 (U/L)	01/06/91	229.00		180.00		203.00	
ALK. PHOSPH.	30-90 (UI/L)	01/06/91	69.00		65.00		75.00	
GLUCOSE	0.75-1.05 (G/L)	01/06/91	0.88		0.94		0.93	
UREA	0.19-0.42 (G/L)	01/06/91	0.37		0.49 >		0.45 >	
CREATININE	0.007-0.014 (G/L)	01/06/91	0.01		0.01		0.01	
URIC ACID	0.03-0.06 (G/L)	01/06/91	0.04		0.04		0.04	
TOT BILIRUBIN	2-10 (MG/L)	01/06/91	5.00		6.00		6.00	
TOT. PROTEINS	60-78 (G/L)	01/06/91	75.30		74.30		76.10	
ALBUMINE	57-61 (%)	01/06/91	57.00		59.00		56.00 <	
TOT. CHOLEST.	1.3-1.7 (G/L)	01/06/91	2.20 >		2.33 >>		2.43 >>	
TRIGLYCERIDES	0.45-1.2 (G/L)	01/06/91	1.14		1.22 >		1.15	
GLOBULINS ALPHA 1	3-5.5 (%)	01/06/91	3.00		3.00		3.00	
GLOBULINS ALPHA 2	7-9.5 (%)	01/06/91	8.50		8.00		9.00	
GLOBULINS BETA	10-14 (%)	01/06/91	12.00		11.50		12.50	
GLOBULINS GAMMA	14-17 (%)	01/06/91	19.50 >		18.50 >		19.50 >	
TSH	0.15-3.5 (UU/ML)	01/06/91	0.32					
T4	45-120 (NG/ML)	01/06/91	73.20					

1724

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done (*) missing range value

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Laboratory test	Range values	Range date	09/06/91		28/06/91		17/	
			value	(€)	value	(€)	value	(€)
HB	12-15.8 (g/dL)	01/05/91	10.70 <		10.30 <		10.50 <	
HT	37-46 (X)	01/05/91	33.30 <		32.80 <		33.50 <	
RBC	4.1-5.2 (10 ⁶ /UL)	01/05/91	5.23 >		5.14		5.27 >	
HBC	4500-10500 (/UL)	01/05/91	6200.00		4600.00		5600.00	
HBC: N	45-74 (X)	01/05/91	50.20		46.50		46.90	
HBC: L	16-45 (X)	01/05/91	38.50		44.00		42.60	
HBC: E	0-7 (X)	01/05/91	5.00		2.90		2.90	
HBC: W	4-10 (X)	01/05/91	0.70 <		6.20		7.10	
HBC: B	0-2 (X)	01/05/91	5.50 >>		0.40		0.40	
PLATELETS	150000-380000 (/UL)	01/05/91			340000		319000	
NA+	137-145 (MEQ/L)	01/05/91			141.00		142.00	
K+	3.8-4.8 (MEQ/L)	01/05/91			3.94		3.84	
CL-	95-107 (MEQ/L)	01/05/91			99.00		103.00	
Ca++	88-105 (MG/L)	01/05/91			93.60		93.60	
PO4--	29-44 (MG/L)	01/05/91			34.00		33.20	
SGOT	5-40 (UI/L)	01/05/91	12.00		17.00		16.00	
SGPT	5-40 (UI/L)	01/05/91	15.00		29.00		24.00	
GAMMA GT	8-40 (UI/L)	01/05/91			13.00		13.00	
LDR	100-300 (UI/L)	01/05/91			145.00		278.00	
ALK. PHOSPH.	30-90 (UI/L)	01/05/91			43.00		41.00	
GLUCOSE	0.75-1.06 (G/L)	01/05/91	0.90		0.87		0.91	
UREA	0.17-0.44 (G/L)	01/05/91			0.23		0.25	
CREATININE	5.65-11.3 (MG/L)	01/05/91	8.70		7.80		8.30	
UREC ACID	25-70 (MG/L)	01/05/91	34.70		29.60		30.10	
TOT. BILIRUBIN	2-13 (MG/L)	01/05/91			6.50		6.60	
TOT. PROTEINS	66-83 (G/L)	01/05/91			76.00		70.00	
ALBUMINE	33-53 (G/L)	01/05/91			39.00		40.00	
TOT. CHOLEST.	1.32-2.35 (G/L)	01/05/91	2.45 >		2.68 >		2.27	
TRIGLYCERIDES	0.3-1.65 (G/L)	01/05/91	0.42		0.38		0.41	
GLOBULINS ALPHA 1	2-4 (X)	01/05/91			2.60		2.70	
GLOBULINS ALPHA 2	6-10 (X)	01/05/91			7.70		9.20	
GLOBULINS BETA	8-12 (X)	01/05/91			9.80		17.30 >>	
GLOBULINS GAMMA	12-19 (X)	01/05/91			17.70		19.90 >	
TSH	0.2-6.2 (MU/UL)	01/05/91	1.49					
T4	7-22 (UG/UL)	01/05/91	13.30					

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 96 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/08/91		25/09/91		25/10/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	07/07/91	13.10		14.30		13.90	
HT	35-47 (%)	07/07/91	38.30		42.70		40.70	
RBC	4-5.2 (10 ⁶ /UL)	07/07/91	4.27		4.70		4.75	
HBC	4000-9000 (/UL)	07/07/91	5800.00		6000.00		7400.00	
HBC: N	50-70 (%)	07/07/91	53.00		50.00		48.00 <	
HBC: L	20-45 (%)	07/07/91	38.00		41.00		43.00	
HBC: E	1-4 (%)	07/07/91	2.00		2.00		2.00	
HBC: M	3-8 (%)	07/07/91	6.00		7.00		7.00	
HBC: B	0-1 (%)	07/07/91	1.00		0.00		0.00	
PLATELETS	150000-400000 (/UL)	07/07/91	254000		327000		328000	
NA+	135-145 (MEQ/L)	07/07/91	142.00		142.00		140.00	
K+	3.6-5.3 (MEQ/L)	07/07/91	4.10		4.10		4.30	
CL-	95-105 (MEQ/L)	07/07/91	101.00		102.00		99.00	
Ca++	90-105 (MG/L)	07/07/91	88.00 <		97.00		92.00	
PO4--	28-45 (MG/L)	07/07/91	33.00		36.00		31.00	
SGOT	6-25 (U/L)	07/07/91	22.00		16.00		27.00 >	
SGPT	7-28 (U/L)	07/07/91	19.00		12.00		8.00	
GAMMA GT	6-26 (U/L)	07/07/91	12.00		11.00		13.00	
LDH	120-280 (U/L)	07/07/91	226.00		223.00		302.00 >	
ALK. PHOSPH.	30-90 (UI/L)	07/07/91	89.00		105.00 >		114.00 >	
GLUCOSE	0.75-1.05 (G/L)	07/07/91	0.99		0.88		0.87	
UREA	0.19-0.42 (G/L)	07/07/91	0.43 >		0.31		0.48 >	
CREATININE	0.006-0.011 (G/L)	07/07/91	0.01		0.01		0.01 >	
URIC ACID	0.03-0.06 (G/L)	07/07/91	0.07 >		0.05		0.05	
TOT BILIRUBIN	2-10 (MG/L)	07/07/91	3.00		5.00		7.00	
TOT. PROTEINS	60-78 (G/L)	07/07/91	69.80		76.60		77.10	
ALBUMINE	57-61 (%)	07/07/91	57.00		55.50 <		56.00 <	
TOT. CHOLEST.	1.3-2 (G/L)	07/07/91	2.38 >		2.27 >		2.39 >	
TRIGLYCERIDES	0.45-1.2 (G/L)	07/07/91	1.19		0.66		0.85	
GLOBULINS ALPHA 1	3-5.5 (%)	07/07/91	2.50 <		3.00		3.00	
GLOBULINS ALPHA 2	7-9.5 (%)	07/07/91	9.00		10.00 >		10.00 >	
GLOBULINS BETA	10-14 (%)	07/07/91	15.00 >		14.50 >		14.50 >	
GLOBULINS GAMMA	14-17 (%)	07/07/91	16.50		17.00		16.50	
TSH	0.15-3.5 (UU/ML)	07/07/91	3.54 >					
T4	45-120 (NG/ML)	07/07/91	61.20					

1726

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 115 Treatment: Raboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/04/92		02/06/92		19/06/92	
			value	(†)	value	(†)	value	(†)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	07/07/91	14.70		15.10		15.20	
HT	35-47 (%)	07/07/91	43.90		44.10		44.50	
RBC	4-5.2 (10 ⁶ /UL)	07/07/91	4.75		4.78		4.90	
WBC	4000-9000 (/UL)	07/07/91	5600.00		5700.00		7000.00	
WBC: N	50-70 (%)	07/07/91	45.00	<	36.00	<	41.00	
WBC: L	20-45 (%)	07/07/91	45.00		53.00	>	48.00	
WBC: E	1-4 (%)	07/07/91	3.00		3.00		4.00	
WBC: M	3-8 (%)	07/07/91	6.00		7.00		6.00	
WBC: B	0-1 (%)	07/07/91	1.00		1.00		1.00	
PLATELETS	150000-400000 (/UL)	07/07/91	344000		311000		384000	
NA+	135-145 (MEQ/L)	07/07/91	140.00		138.00		135.00	
K+	3.6-5.3 (MEQ/L)	07/07/91	4.30		4.40		3.80	
CL-	95-105 (MEQ/L)	07/07/91	102.00		99.00		94.00	
Ca++	90-105 (MG/L)	07/07/91	98.00		93.00		97.00	
PO4--	28-45 (MG/L)	07/07/91	29.00		28.00		32.00	
SGOT	6-25 (U/L)	07/07/91	23.00		18.00		14.00	
SGPT	7-28 (U/L)	07/07/91	15.00		12.00		9.00	
GAMMA GT	6-26 (U/L)	07/07/91	21.00		20.00		15.00	
LDH	120-280 (U/L)	07/07/91	188.00		203.00		197.00	
ALK. PHOSPH.	30-90 (UI/L)	07/07/91	93.00	>	81.00		84.00	
GLUCOSE	0.75-1.05 (G/L)	07/07/91	1.08	>	0.89		0.86	
UREA	0.19-0.42 (G/L)	07/07/91	0.37		0.29		0.43	
CREATININE	0.006-0.011 (G/L)	07/07/91	0.01		0.01		0.01	
URIC ACID	0.03-0.06 (G/L)	07/07/91	0.04		0.06		0.05	
TOT BILIRUBIN	2-10 (MG/L)	07/07/91	4.00		7.00		8.00	
TOT. PROTEINS	60-78 (G/L)	07/07/91	77.60		72.90		73.10	
ALBUMINE	57-61 (%)	07/07/91	62.00	>	61.00		58.00	
TOT. CHOLEST.	1.3-2 (G/L)	07/07/91	2.69	>>	2.24	>	2.33	
TRIGLYCERIDES	0.45-1.2 (G/L)	07/07/91	1.09		0.96		1.28	
GLOBULINS ALPHA 1	3-5.5 (%)	07/07/91	3.50		3.00		3.50	
GLOBULINS ALPHA 2	7-9.5 (%)	07/07/91	7.50		8.50		9.00	
GLOBULINS BETA	10-14 (%)	07/07/91	13.00		13.00		14.50	
GLOBULINS GAMMA	14-17 (%)	07/07/91	14.00		14.50		15.00	
TSH	0.15-3.5 (UU/ML)	07/07/91	0.26					
T4	45-120 (NG/ML)	07/07/91	66.90					

1727

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 116 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			09/05/92
			value (†)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	07/07/91	13.50
HT	35-47 (Z)	07/07/91	40.40
RBC	4-5.2 (10 ⁶ /UL)	07/07/91	4.41
WBC	4000-9000 (/UL)	07/07/91	8300.00
WBC: N	50-70 (Z)	07/07/91	59.00
WBC: L	20-45 (Z)	07/07/91	31.00
WBC: E	1-4 (Z)	07/07/91	3.00
WBC: M	3-8 (Z)	07/07/91	6.00
WBC: B	0-1 (Z)	07/07/91	1.00
PLATELETS	150000-400000 (/UL)	07/07/91	200000
NA+	135-145 (MEQ/L)	07/07/91	141.00
K+	3.6-5.3 (MEQ/L)	07/07/91	4.10
CL-	95-105 (MEQ/L)	07/07/91	99.00
Ca++	90-105 (MG/L)	07/07/91	93.00
PO4--	28-45 (MG/L)	07/07/91	33.00
SGOT	6-25 (U/L)	07/07/91	17.00
SGPT	7-28 (U/L)	07/07/91	14.00
GAMMA GT	6-26 (U/L)	07/07/91	10.00
LDH	120-280 (U/L)	07/07/91	175.00
ALK. PHOSPH.	30-90 (UI/L)	07/07/91	37.00
GLUCOSE	0.75-1.05 (G/L)	07/07/91	0.86
UREA	0.19-0.42 (G/L)	07/07/91	0.34
CREATININE	0.006-0.011 (G/L)	07/07/91	0.01
URIC ACID	0.03-0.06 (G/L)	07/07/91	0.03
TOT BILIRUBIN	2-10 (MG/L)	07/07/91	5.00
TOT. PROTEINS	60-78 (G/L)	07/07/91	66.50
ALBUMINE	57-61 (Z)	07/07/91	58.50
TOT. CHOLEST.	1.3-2 (G/L)	07/07/91	2.14 >
TRIGLYCERIDES	0.45-1.2 (G/L)	07/07/91	0.78
GLOBULINS ALPHA 1	3-5.5 (Z)	07/07/91	3.50
GLOBULINS ALPHA 2	7-9.5 (Z)	07/07/91	8.00
GLOBULINS BETA	10-14 (Z)	07/07/91	12.00
GLOBULINS GAMMA	14-17 (Z)	07/07/91	18.00 >
TSH	0.15-3.5 (UU/ML)	07/07/91	1.86
T4	45-120 (NG/ML)	07/07/91	81.50

1728

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 117 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			29/08/91		24/09/91		15/10/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	07/07/91	13.20		13.90		13.90	
HT	35-47 (%)	07/07/91	39.00		40.80		39.90	
RBC	4-5.2 (10 ⁶ /UL)	07/07/91	4.49		4.64		4.61	
WBC	4000-9000 (/UL)	07/07/91	4000.00		4000.00		3400.00 <	
WBC: N	50-70 (%)	07/07/91	44.00 <		45.00 <		39.00 <	
WBC: L	20-45 (%)	07/07/91	41.00		40.00		44.00	
WBC: E	1-4 (%)	07/07/91	5.00 >		6.00 >>		6.00 >>	
WBC: M	3-8 (%)	07/07/91	9.00 >		9.00 >		10.00 >	
WBC: B	0-1 (%)	07/07/91	1.00		0.00		1.00	
PLATELETS	150000-400000 (/UL)	07/07/91	257000		281000		239000	
NA+	135-145 (MEQ/L)	07/07/91	142.00		141.00		138.00	
K+	3.6-5.3 (MEQ/L)	07/07/91	4.00		4.50		4.50	
CL-	95-105 (MEQ/L)	07/07/91	101.00		101.00		95.00	
Ca++	90-105 (MG/L)	07/07/91	97.00		99.00		96.00	
PO4--	28-45 (MG/L)	07/07/91	29.00		39.00		29.00	
SGOT	6-25 (U/L)	07/07/91	12.00		19.00		21.00	
SGPT	7-28 (U/L)	07/07/91	15.00		37.00 >		24.00	
GAMMA GT	6-26 (U/L)	07/07/91	23.00		38.00 >		36.00 >	
LDH	120-280 (U/L)	07/07/91	227.00		228.00		215.00	
ALK. PHOSPH.	30-90 (UI/L)	07/07/91	78.00		113.00 >		119.00 >	
GLUCOSE	0.75-1.05 (G/L)	07/07/91	0.93		0.81		0.77	
UREA	0.19-0.42 (G/L)	07/07/91	0.30		0.35		0.31	
CREATININE	0.006-0.011 (G/L)	07/07/91	0.01		0.01		0.01	
URIC ACID	0.03-0.06 (G/L)	07/07/91	0.03 <		0.03 <		0.03 <	
TOT BILIRUBIN	2-10 (MG/L)	07/07/91	4.00		3.00		4.00	
TOT. PROTEINS	60-78 (G/L)	07/07/91	60.40		65.90		66.50	
ALBUMINE	57-61 (%)	07/07/91	58.50		58.00		58.00	
TOT. CHOLEST.	1.3-2 (G/L)	07/07/91	2.06 >		2.49 >		2.26 >	
TRIGLYCERIDES	0.45-1.2 (G/L)	07/07/91	1.33 >		0.99		1.03	
GLOBULINS ALPHA 1	3-5.5 (%)	07/07/91	5.00		5.00		4.50	
GLOBULINS ALPHA 2	7-9.5 (%)	07/07/91	11.00 >		11.50 >		11.00 >	
GLOBULINS BETA	10-14 (%)	07/07/91	14.50 >		15.00 >		14.50 >	
GLOBULINS GAMMA	14-17 (%)	07/07/91	11.00 <		10.50 <		12.00 <	
TSH	0.15-3.5 (UU/ML)	07/07/91	0.04 <<					
T4	45-120 (NG/ML)	07/07/91	118.10					

1729

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 118 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Day 21		Day 42	
			13/06/92		04/07/92	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	07/07/91	13.90		14.20	
HT	35-47 (X)	07/07/91	40.20		40.80	
RBC	4-5.2 (10 ⁶ /UL)	07/07/91	4.31		4.35	
MBC	4000-9000 (/UL)	07/07/91	7100.00		9400.00 >	
MBC: M	50-70 (X)	07/07/91	59.00		65.00	
MBC: L	20-45 (X)	07/07/91	29.00		24.00	
MBC: E	1-4 (X)	07/07/91	2.00		2.00	
MBC: M	3-8 (X)	07/07/91	9.00 >		8.00	
MBC: B	0-1 (X)	07/07/91	1.00		1.00	
PLATELETS	150000-400000 (/UL)	07/07/91	229000		275000	
NA+	135-145 (MEQ/L)	07/07/91	139.00		140.00	
K+	3.6-5.3 (MEQ/L)	07/07/91	4.30		4.60	
CL-	95-105 (MEQ/L)	07/07/91	100.00		102.00	
Ca++	90-105 (MG/L)	07/07/91	95.00		87.00 <	
PO4--	28-45 (MG/L)	07/07/91	45.00		28.00	
SGOT	6-25 (U/L)	07/07/91	27.00 >		30.00 >	
SGPT	7-28 (U/L)	07/07/91	20.00		28.00	
GAMMA GT	6-26 (U/L)	07/07/91	41.00 >		31.00 >	
LDH	120-280 (U/L)	07/07/91	334.00 >		266.00	
ALK. PHOSPH.	30-90 (UI/L)	07/07/91	90.00		77.00	
GLUCOSE	0.75-1.05 (G/L)	07/07/91	0.99		1.01	
UREA	0.19-0.42 (G/L)	07/07/91	0.37		0.33	
CREATININE	0.006-0.011 (G/L)	07/07/91	0.01		0.01	
URIC ACID	0.03-0.06 (G/L)	07/07/91	0.03		0.03	
TOT BILIRUBIN	2-10 (MG/L)	07/07/91	3.00		3.00	
TOT. PROTEINS	60-78 (G/L)	07/07/91	70.60		65.50	
ALBUMINE	57-61 (X)	07/07/91	55.00 <		60.00	
TOT. CHOLEST.	1.3-2 (G/L)	07/07/91	2.09 >		1.99	
TRIGLYCERIDES	0.45-1.2 (G/L)	07/07/91	1.03		0.90	
GLOBULINS ALPHA 1	3-5.5 (X)	07/07/91	4.00		4.00	
GLOBULINS ALPHA 2	7-9.5 (X)	07/07/91	11.50 >		8.50	
GLOBULINS BETA	10-14 (X)	07/07/91	13.00		12.00	
GLOBULINS GAMMA	14-17 (X)	07/07/91	16.50		15.50	

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1730

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 119 Treatment: Placebo Sex: Female

			Visit number / Laboratory date
			Screen
			16/03/92
			value (€)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	07/07/91	13.10
HT	35-47 (X)	07/07/91	38.00
RBC	4-5.2 (10 ⁶ /UL)	07/07/91	4.15
MBC	4000-9000 (/UL)	07/07/91	4100.00
MBC: N	50-70 (X)	07/07/91	60.00
MBC: L	20-45 (X)	07/07/91	31.00
MBC: E	1-4 (X)	07/07/91	1.00
MBC: M	3-8 (X)	07/07/91	7.00
MBC: B	0-1 (X)	07/07/91	1.00
PLATELETS	150000-400000 (/UL)	07/07/91	248000
NA+	135-145 (MEQ/L)	07/07/91	139.00
K+	3.6-5.3 (MEQ/L)	07/07/91	4.20
CL-	95-105 (MEQ/L)	07/07/91	99.00
Ca++	90-105 (MG/L)	07/07/91	98.00
PO4--	28-45 (MG/L)	07/07/91	34.00
SGOT	6-25 (U/L)	07/07/91	11.00
SGPT	7-28 (U/L)	07/07/91	16.00
GAMMA GT	6-26 (U/L)	07/07/91	9.00
LDH	120-280 (U/L)	07/07/91	201.00
ALK. PHOSPH.	30-90 (UI/L)	07/07/91	36.00
GLUCOSE	0.75-1.05 (G/L)	07/07/91	1.02
UREA	0.19-0.42 (G/L)	07/07/91	0.26
CREATININE	0.006-0.011 (G/L)	07/07/91	0.01
URIC ACID	0.03-0.06 (G/L)	07/07/91	0.03
TOT BILIRUBIN	2-10 (NG/L)	07/07/91	6.00
TOT. PROTEINS	60-78 (G/L)	07/07/91	73.90
ALBUMINE	57-61 (X)	07/07/91	61.50 >
TOT. CHOLEST.	1.3-2 (G/L)	07/07/91	2.77 >>
TRIGLYCERIDES	0.45-1.2 (G/L)	07/07/91	0.62
GLOBULINS ALPHA 1	3-5.5 (X)	07/07/91	3.50
GLOBULINS ALPHA 2	7-9.5 (X)	07/07/91	8.00
GLOBULINS BETA	10-14 (X)	07/07/91	14.50 >
GLOBULINS GAMMA	14-17 (X)	07/07/91	12.50 <
TSH	0.15-3.5 (UU/ML)	07/07/91	0.66
T4	45-120 (NG/ML)	07/07/91	73.10

1731

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 120 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/06/92		21/08/92		22/09/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	120-160 (G/L)	04/05/92	127.00		131.00		124.00	
HT	37-52 (%)	04/05/92	37.20		39.40		38.00	
RBC	4000000-5400000 (/MM3)	04/05/92						
			4200000		4490000		4350000	
HBC	4000-10000 (/UL)	04/05/92	5000.00		5100.00		5800.00	
HBC: N	50-70 (%)	04/05/92	55.20		66.00		64.20	
HBC: L	20-30 (%)	04/05/92	35.90	>	27.90		27.10	
HBC: E	1-2 (%)	04/05/92	2.80	>>	2.00		2.30	>
HBC: M	5-8 (%)	04/05/92	5.80		3.70	<	6.10	
HBC: B	0-1 (%)	04/05/92	0.10		0.10		0.00	
PLATELETS	150000-400000 (/UL)	04/05/92						
			189000		203000		163000	
NA+	135-145 (MEQ/L)	04/05/92	142.00		144.00		140.00	
K+	3.5-5.5 (MEQ/L)	04/05/92	4.30		3.80		4.20	
CL-	95-105 (MEQ/L)	04/05/92	102.00		106.00	>	103.00	
Ca++	84-102 (MG/L)	04/05/92	91.00		93.00		90.00	
PO4--	25-45 (MG/L)	04/05/92	37.00		38.00		36.00	
SGOT	7-45 (UI/L)	04/05/92	26.00		33.00		27.00	
SGPT	5-56 (UI/L)	04/05/92	65.00	>	44.00		40.00	
GAMMA GT	8-78 (UI/L)	04/05/92	74.00		43.00		35.00	
LDH	313-618 (UI/L)	04/05/92	319.00		338.00		313.00	
ALK. PHOSPH.	37-123 (UI/L)	04/05/92	58.00		76.00		66.00	
GLUCOSE	0.75-1.1 (G/L)	04/05/92	0.87		0.84		0.85	
UREA	0.1-0.45 (G/L)	04/05/92	0.28		0.25		0.28	
CREATININE	4-15 (MG/L)	04/05/92	10.00		11.00		9.00	
URIC ACID	30-70 (MG/L)	04/05/92	49.00		65.00		58.00	
TOT BILIRUBIN	2-10 (MG/L)	04/05/92	4.00		6.00		5.00	
TOT. PROTEINS	60-82 (G/L)	04/05/92	68.00		72.00		73.00	
ALBUMINE	35-45 (G/L)	04/05/92	44.88		44.64		43.07	
TOT. CHOLEST.	1.5-2 (G/L)	04/05/92	2.04	>	2.48	>	1.99	
TRIGLYCERIDES	0.4-1.6 (G/L)	04/05/92	1.20		1.26		0.80	
GLOBULINS ALPHA 1	2-4 (G/L)	04/05/92	1.36	<<	2.16		2.19	
GLOBULINS ALPHA 2	5-7 (G/L)	04/05/92	4.76	<	5.76		5.84	
GLOBULINS BETA	7-11 (G/L)	04/05/92	7.48		9.36		10.22	
GLOBULINS GAMMA	8-14 (G/L)	04/05/92	9.52		10.08		11.68	
TSH	0.32-5 (UU/ML)	04/05/92	0.00	<<	0.90		1.12	
T4	7-18 (PG/ML)	04/05/92	16.20		10.20		11.50	

1732

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 145 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			30/09/92		30/10/92	
			value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	25/09/92	9.30	<<		
HT	37-47 (X)	25/09/92	29.50	<<		
RBC	4.2-5.4 (10 ⁶ /UL)	25/09/92	4.21			
NBC	4.8-10.8 (10 ³ /UL)	25/09/92	5.71			
NBC: N	40-74 (X)	25/09/92	65.00			
NBC: L	19-48 (X)	25/09/92	26.00			
NBC: E	0-7 (X)	25/09/92	4.00			
NBC: M	3.4-9 (X)	25/09/92	4.00			
NBC: B	0-1.5 (X)	25/09/92	1.00			
PLATELETS	130-400 (10 ³ /UL)	25/09/92	317.00			
NA+	137-145 (MEQ/L)	25/09/92	138.00		136.00	<
K+	3.6-5 (MEQ/L)	25/09/92	4.50		4.00	
CL-	101-111 (MEQ/L)	25/09/92	104.00		100.00	<
Ca++	84-102 (MG/L)	25/09/92	97.00		96.00	
PO4--	25-45 (MG/L)	25/09/92	32.00		35.00	
SGOT	5-35 (U/L)	25/09/92	15.00		14.00	
SGPT	7-56 (U/L)	25/09/92	26.00		20.00	
GAMMA GT	8-78 (U/L)	25/09/92	19.00		18.00	
LDH	313-618 (U/L)	25/09/92	439.00		391.00	
ALK. PHOSPH.	38-126 (U/L)	25/09/92	50.00		61.00	
GLUCOSE	0.65-1.05 (G/L)	25/09/92	0.94		0.87	
UREA	0.15-0.45 (G/L)	25/09/92	0.29		0.24	
CREATININE	5-12 (NG/L)	25/09/92	10.00		11.00	
URIC ACID	25-62 (NG/L)	25/09/92	33.00		34.00	
TOT BILIRUBIN	2-13 (NG/L)	25/09/92	4.50		4.90	
DIR BILIRUBIN	0-3 (NG/L)	25/09/92	0.00		0.00	
TOT. PROTEINS	63-82 (G/L)	25/09/92	67.00		71.00	
ALBUMINE	57-65 (X)	25/09/92	53.40	<	62.90	
TOT. CHOLEST.	1.1-2 (G/L)	25/09/92	2.54	>	2.31	>
TRIGLYCERIDES	0.35-1.35 (G/L)	25/09/92	0.86		0.88	
GLOBULINS ALPHA 1	2-4 (X)	25/09/92	4.00		3.10	
GLOBULINS ALPHA 2	6-10 (X)	25/09/92	10.20	>	7.80	
GLOBULINS BETA	8-12 (X)	25/09/92	16.50	>>	11.80	
GLOBULINS GAMMA	12-19 (X)	25/09/92	15.90		14.40	
TSH	0.16-3.5 (MUI/L)	25/09/92	1.31			
T4	9-25 (PMOL/L)	25/09/92	15.10			

1733

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 146 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/08/92		05/10/92		27/10/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/07/92	13.80		13.90		13.40	
HT	37-52 (%)	01/07/92	41.30		41.80		40.20	
RBC	4000000-5500000 (/UL)	01/07/92						
			4800000		4880000		4670000	
HBC	4000-9000 (/UL)	01/07/92	3100.00 <		3600.00 <		3100.00 <	
HBC: N	50-70 (%)	01/07/92	51.00		59.00		50.00	
HBC: L	20-30 (%)	01/07/92	37.00 >		33.00 >		40.00 >>	
HBC: E	1-2 (%)	01/07/92	0.00 <		0.00 <		1.00	
HBC: M	5-8 (%)	01/07/92	9.00 >		8.00		9.00 >	
HBC: B	0-1 (%)	01/07/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/UL)	01/07/92						
			209000		219000		223000	
NA+	135-143 (MEQ/L)	01/07/92	141.00		142.00		143.00	
K+	3.7-4.8 (MEQ/L)	01/07/92	4.30		4.40		4.30	
CL-	95-108 (MEQ/L)	01/07/92	103.00		108.00		107.00	
Ca++	88-102 (MG/L)	01/07/92	96.00		97.00		98.00	
PO4--	25-50 (MG/L)	01/07/92	35.00		37.00		34.00	
SGOT	5-22 (UI/L)	01/07/92	23.00 >		24.00 >		27.00 >	
SGPT	5-24 (UI/L)	01/07/92	13.00		12.00		12.00	
GAMMA GT	5-25 (UI/L)	01/07/92	9.00		9.00		9.00	
LDH	140-330 (UI/L)	01/07/92	228.00		222.00		260.00	
ALK. PHOSPH.	50-210 (UI/L)	01/07/92	192.00		229.00 >		197.00	
GLUCOSE	0.75-1.1 (G/L)	01/07/92	1.01		1.01		1.00	
UREA	0.2-0.4 (G/L)	01/07/92	0.29		0.27		0.22	
CREATININE	4-13 (MG/L)	01/07/92	8.00		8.00		8.00	
URIC ACID	0.03-0.055 (G/L)	01/07/92	0.04		0.04		0.04	
TOT BILIRUBIN	3-10 (MG/L)	01/07/92	5.00		5.00		5.00	
TOT. PROTEINS	60-80 (G/L)	01/07/92	72.00		71.00		83.00 >	
ALBUMINE	32-50 (G/L)	01/07/92	42.30		43.70		48.40	
TOT. CHOLEST.	1.3-2.2 (G/L)	01/07/92	2.99 >>		2.97 >>		2.76 >	
TRIGLYCERIDES	0.5-1.5 (G/L)	01/07/92	1.60 >		1.71 >		1.59 >	
GLOBULINS ALPHA 1	1-4 (G/L)	01/07/92	2.10		1.60		2.20	
GLOBULINS ALPHA 2	5-11 (G/L)	01/07/92	6.60		6.00		7.80	
GLOBULINS BETA	6-15 (G/L)	01/07/92	9.40		8.90		9.10	
GLOBULINS GAMMA	7-15 (G/L)	01/07/92	11.70		10.90		15.80 >	
TSH	0.3-5 (UUI/ML)	01/07/92	1.52					
T4	4.9-12.5 (UG/DL)	01/07/92	8.48					

1734

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/1 Patient: 147 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/07/92		21/09/92		13/10/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/07/92	14.00		13.80		13.90	
HT	37-52 (X)	01/07/92	43.90		42.00		43.20	
RBC	4000000-5500000 (/UL)	01/07/92						
			4870000		4780000		4940000	
WBC	4000-9000 (/UL)	01/07/92	6400.00		6710.00		6600.00	
WBC: N	50-70 (%)	01/07/92	55.40		66.00		63.70	
WBC: L	20-30 (%)	01/07/92	33.60 >		26.00		26.80	
WBC: E	1-2 (%)	01/07/92	1.90		2.60 >		>>	
WBC: M	5-8 (%)	01/07/92	8.10 >		4.50 <		6.10	
WBC: B	0-1 (%)	01/07/92	1.00		0.90		0.70	
PLATELETS	150000-400000 (/UL)	01/07/92						
					197000		204000	
NA+	135-145 (MEQ/L)	01/07/92	143.00		143.00		144.00	
K+	3.5-5 (MEQ/L)	01/07/92	3.90		4.10		4.20	
CL-	95-105 (MEQ/L)	01/07/92	103.00		100.00		99.00	
Ca++	88-102 (MG/L)	01/07/92	95.00		99.00		92.00	
PO4--	25-40 (MG/L)	01/07/92	40.00		44.00 >		40.00	
SGOT	10-37 (UI/L)	01/07/92	16.00		15.00		14.00	
SGPT	10-40 (UI/L)	01/07/92	26.00		24.00		21.00	
GAMMA GT	11-43 (UI/L)	01/07/92	39.00		35.00		27.00	
LDH	200-480 (U/L)	01/07/92	238.00		285.00		280.00	
ALK. PHOSPH.	100-290 (UI/L)	01/07/92	110.00		102.00		108.00	
GLUCOSE	0.75-1.15 (G/L)	01/07/92	1.38 >		1.19 >		1.18 >	
UREA	0.2-0.4 (G/L)	01/07/92	0.27		0.31		0.28	
CREATININE	6-15 (MG/L)	01/07/92	11.00		10.00		10.00	
URIC ACID	25-70 (MG/L)	01/07/92	69.00		74.00 >		78.00 >	
TOT BILIRUBIN	2-10 (MG/L)	01/07/92	2.00		3.00		3.00	
TOT. PROTEINS	60-78 (G/L)	01/07/92	60.00		63.00		68.00	
ALBUMINE	35-53 (G/L)	01/07/92	36.90		38.30		40.30	
TOT. CHOLEST.	1.3-2 (G/L)	01/07/92	2.84 >>		2.58 >		2.60 >	
TRIGLYCERIDES	0.4-1.55 (G/L)	01/07/92	3.06 >>		2.73 >>		4.00 >>	
GLOBULINS ALPHA 1	1.2-3.9 (G/L)	01/07/92	2.04		2.14		2.38	
GLOBULINS ALPHA 2	3.6-8.6 (G/L)	01/07/92	6.36		6.43		7.28	
GLOBULINS BETA	5-11 (G/L)	01/07/92	8.27		9.01		10.60	
GLOBULINS GAMMA	7-15 (G/L)	01/07/92	6.42 <		7.12		7.48	
TSH	0.15-3.9 (MUI/L)	01/07/92	2.16				3.12	
T4	4-12 (UG/100ML)	01/07/92	10.10				10.00	

1735

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 148 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/09/92		20/10/92		10/11/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/09/92	13.30		14.20		13.70	
HT	37-52 (X)	01/09/92	42.10		44.60		42.90	
RBC	4000000-5500000 (/UL)	01/09/92						
			4700000		4990000		4720000	
HBC	4000-9000 (/UL)	01/09/92	6650.00		6880.00		7470.00	
HBC: N	50-70 (%)	01/09/92	50.70		58.30		51.70	
HBC: L	20-30 (%)	01/09/92	36.30 >		30.70 >>		36.90 >	
HBC: E	1-2 (%)	01/09/92	4.00 >>		3.40 >>		3.20 >>	
HBC: M	5-8 (%)	01/09/92	7.80		6.60		7.00	
HBC: B	0-1 (%)	01/09/92	1.20 >		1.00		1.20 >	
PLATELETS	150000-400000 (/UL)	01/09/92						
			219000		239000		225000	
NA+	135-145 (MEQ/L)	01/09/92	138.00		139.00		137.00	
K+	3.5-5 (MEQ/L)	01/09/92	4.50		4.80		4.40	
CL-	95-105 (MEQ/L)	01/09/92	99.00		93.00 <		98.00	
Ca++	88-102 (MG/L)	01/09/92	93.00		96.00		94.00	
PO4--	25-40 (MG/L)	01/09/92	33.00		53.00 >>		38.00	
SGOT	10-37 (UI/L)	01/09/92	19.00		64.00 >		16.00	
SGPT	10-40 (UI/L)	01/09/92	33.00		113.00 >>		26.00	
GAMMA GT	11-43 (UI/L)	01/09/92	17.00		25.00		27.00	
LDH	200-480 (U/L)	01/09/92	332.00		325.00		302.00	
ALK. PHOSPH.	100-290 (UI/L)	01/09/92	108.00		148.00		138.00	
GLUCOSE	0.75-1.15 (G/L)	01/09/92	1.04		0.93		0.95	
UREA	0.2-0.4 (G/L)	01/09/92	0.31		0.48 >		0.33	
CREATININE	6-15 (MG/L)	01/09/92	10.00		11.00		10.00	
URIC ACID	25-70 (MG/L)	01/09/92	47.00		53.00		50.00	
TOT BILIRUBIN	2-10 (MG/L)	01/09/92	5.00		3.00		3.00	
TOT. PROTEINS	60-78 (G/L)	01/09/92	68.00		77.00		73.00	
ALBUMINE	35-53 (G/L)	01/09/92	35.50		44.70		43.40	
TOT. CHOLEST.	1.3-2 (G/L)	01/09/92	1.95		2.61 >>		2.18 >	
TRIGLYCERIDES	0.4-1.55 (G/L)	01/09/92	1.68 >		2.13 >>		1.94 >	
GLOBULINS ALPHA 1	1.2-3.9 (G/L)	01/09/92	2.45		1.77		1.31	
GLOBULINS ALPHA 2	3.6-8.6 (G/L)	01/09/92	8.09		7.70		6.57	
GLOBULINS BETA	5-11 (G/L)	01/09/92	8.57		9.39		8.18	
GLOBULINS GAMMA	7-15 (G/L)	01/09/92	13.40		13.40		13.60	
TSH	0.15-3.9 (MUI/L)	01/09/92	1.72					
T4	4-12 (UG/100ML)	01/09/92	6.20					

1736

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 149 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/09/92		21/10/92		18/11/92	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	20/09/92	15.40		15.60		15.50	
HT	37-52 (%)	20/09/92	46.50		46.30		45.90	
RBC	4000000-5500000 (/UL)	20/09/92						
			5100000		5100000		5000000	
MBC	4000-9000 (/UL)	20/09/92	7800.00		8000.00		6400.00	
MBC: N	50-70 (%)	20/09/92	62.00		57.00		55.00	
MBC: L	20-30 (%)	20/09/92	22.00		23.00		29.00	
MBC: E	1-2 (%)	20/09/92	4.00	>>	4.00	>>	4.00 >>	
MBC: M	5-8 (%)	20/09/92	11.00	>>	14.00	>>	11.00 >>	
MBC: B	0-1 (%)	20/09/92	1.00	>>	2.00	>>	1.00	
PLATELETS	150000-400000 (/UL)	20/09/92						
			302000		296000		273000	
NA+	135-143 (MEQ/L)	20/09/92	139.00		141.00		142.00	
K+	3.7-4.8 (MEQ/L)	20/09/92	4.10		3.90		4.40	
CL-	95-108 (MEQ/L)	20/09/92	101.00		100.00		101.00	
Ca++	88-102 (MG/L)	20/09/92	96.00		99.00		100.00	
PO4--	25-50 (MG/L)	20/09/92	28.00		31.00		34.00	
SGOT	5-22 (UI/L)	20/09/92	12.00		15.00		25.00 >	
SGPT	5-24 (UI/L)	20/09/92	16.00		14.00		18.00	
GAMMA GT	5-25 (UI/L)	20/09/92	31.00	>	19.00		28.00 >	
LDH	140-330 (UI/L)	20/09/92	168.00		179.00		192.00	
ALK. PHOSPH.	50-210 (UI/L)	20/09/92	60.00		51.00		56.00	
GLUCOSE	0.75-1.1 (G/L)	20/09/92	1.09		1.01		1.01	
UREA	0.2-0.4 (G/L)	20/09/92	0.28		0.31		0.26	
CREATININE	0.007-0.014 (G/L)	20/09/92	0.01		0.01		0.01	
URIC ACID	0.03-0.055 (G/L)	20/09/92	0.04		0.05		0.04	
TOT BILIRUBIN	3-10 (MG/L)	20/09/92	7.00		9.00		4.00	
TOT. PROTEINS	60-80 (G/L)	20/09/92	69.10		68.50		72.70	
ALBUMINE	32-50 (G/L)	20/09/92	58.00	>	59.50	>	59.00 >	
TOT. CHOLEST.	1.3-2.2 (G/L)	20/09/92	2.22	>	2.22	>	2.51 >	
TRIGLYCERIDES	0.5-1.5 (G/L)	20/09/92	0.60		0.73		0.44 <	
GLOBULINS ALPHA 1	1-4 (G/L)	20/09/92	4.00		5.00	>	4.50 >	
GLOBULINS ALPHA 2	5-11 (G/L)	20/09/92	8.50		8.00		7.50	
GLOBULINS BETA	6-15 (G/L)	20/09/92	13.50		13.00		13.50	
GLOBULINS GAMMA	7-15 (G/L)	20/09/92	16.00	>	14.50		15.50 >	
TSH	0.3-5 (UUI/ML)	20/09/92	1.06					
T4	4.9-12.5 (UG/DL)	20/09/92	12.50					

1737

(ø) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/1 Patient: 150 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/09/92		15/10/92		10/11/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	20/09/92	15.00		15.40		15.60	
HT	35-47 (%)	20/09/92	44.70		46.40		46.50	
RBC	4-5.2 (10 ⁶ /MM ³)	20/09/92	5.17		5.33	>	5.36 >	
WBC	4000-9000 (/MM ³)	20/09/92	6600.00		7100.00		7100.00	
WBC: N	1500-7000 (/MM ³)	20/09/92	3630.00		3763.00			
	50-70 (%)	05/11/92					54.00	
WBC: L	800-4500 (/MM ³)	20/09/92	1980.00		2272.00			
	20-45 (%)	05/11/92					31.00	
WBC: E	0-400 (/MM ³)	20/09/92	396.00		426.00	>		
	1-4 (%)	05/11/92					7.00 >>	
WBC: M	200-800 (/MM ³)	20/09/92	528.00		639.00			
	3-8 (%)	05/11/92					8.00	
WBC: B	0-100 (/MM ³)	20/09/92	66.00		0.00			
	0-1 (%)	05/11/92					0.00	
PLATELETS	150000-400000 (/MM ³)	20/09/92						
			191000		200000			
NA+	135-145 (MEQ/L)	20/09/92	142.00		141.00		137.00	
K+	3.6-5.3 (MEQ/L)	20/09/92	4.40		4.60		4.40	
CL-	95-105 (MEQ/L)	20/09/92	102.00		101.00		98.00	
Ca++	90-105 (MG/L)	20/09/92	97.00		94.00		94.00	
PO4--	28-45 (MG/L)	20/09/92	34.00		33.00		32.00	
SGOT	6-25 (U/L)	20/09/92	21.00		16.00		12.00	
SGPT	7-28 (U/L)	20/09/92	29.00	>	18.00		14.00	
GAMMA GT	6-26 (U/L)	20/09/92	26.00		35.00	>	31.00 >	
LDH	120-280 (U/L)	20/09/92	236.00		210.00		219.00	
ALK. PHOSPH.	30-90 (UI/L)	20/09/92	64.00		66.00		64.00	
GLUCOSE	0.75-1.05 (G/L)	20/09/92	1.13	>	1.02		1.18 >	
UREA	0.19-0.42 (G/L)	20/09/92	0.42		0.42		0.40	
CREATININE	0.006-0.011 (G/L)	20/09/92	0.01	>	0.01		0.01	
URIC ACID	0.03-0.06 (G/L)	20/09/92	0.05		0.05		0.05	
TOT BILIRUBIN	2-10 (MG/L)	20/09/92	5.00		3.00		4.00	
TOT. PROTEINS	60-78 (G/L)	20/09/92	69.30		67.80		66.10	
ALBUMINE	57-61 (%)	20/09/92	60.00		60.50		61.00	
TOT. CHOLEST.	1.4-2 (G/L)	20/09/92	2.15	>	2.45	>	2.42 >	
TRIGLYCERIDES	0.5-2 (G/L)	20/09/92	2.78	>>	4.75	>>	4.19 >>	
GLOBULINS ALPHA 1	3-5.5 (%)	20/09/92	3.50		3.00		3.00	
GLOBULINS ALPHA 2	7-9.5 (%)	20/09/92	8.50		9.00		8.50	
GLOBULINS BETA	10-14 (%)	20/09/92	15.00	>	14.50	>	14.50 >	
GLOBULINS GAMMA	14-17 (%)	20/09/92	13.00	<	13.00	<	13.00 <	
TSH	0.15-3.5 (UU/ML)	20/09/92	1.40					
T4	7.8-19.4 (PG/ML)	20/09/92	9.80					

1738

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/2 Patient: 93/A Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			23/02/91		18/03/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	125-160 (G/L)	01/02/91	149.00		143.00	
HT	0.37-0.54 (L/L)	01/02/91	0.45		0.44	
RBC	4-5.5 (10 ¹² /L)	01/02/91	5.13		4.89	
MBC	4-10 (10 ⁹ /L)	01/02/91	8.30		7.00	
MBC: N	1500-7500 (/MM3)	01/02/91	4814.00		3920.00	
MBC: L	1000-4000 (/MM3)	01/02/91	2988.00		2660.00	
MBC: E	50-300 (/MM3)	01/02/91	166.00		140.00	
MBC: M	100-800 (/MM3)	01/02/91	332.00		280.00	
MBC: B	0-100 (/MM3)	01/02/91	0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	01/02/91	256.00		263.00	
NA+	137-147 (MMOL/L)	01/02/91	141.00		135.00 <	
K+	3.5-5 (MMOL/L)	01/02/91	4.50		4.40	
CL-	98-107 (MMOL/L)	01/02/91	99.00		102.00	
Ca++	2.2-2.5 (MMOL/L)	01/02/91	2.40		2.41	
PO4--	0.8-1.6 (MMOL/L)	01/02/91	0.97		1.16	
SGOT	9-30 (UI/L)	01/02/91	15.00		20.00	
SGPT	8-42 (UI/L)	01/02/91	16.00		14.00	
GAMMA GT	8-33 (UI/L)	01/02/91	27.00		57.00 >	
LDH	140-330 (UI/L)	01/02/91	130.00 <		182.00	
ALK. PHOSPH.	80-220 (UI/L)	01/02/91	110.00		96.00	
GLUCOSE	4.1-6.1 (MMOL/L)	01/02/91	5.05		4.94	
UREA	3-7.5 (MMOL/L)	01/02/91	5.66		5.66	
CREATININE	71-106 (UMOL/L)	01/02/91	106.08 >		106.08 >	
URIC ACID	180-420 (UMOL/L)	01/02/91	417.00		506.00 >	
TOT BILIRUBIN	5-17 (UMOL/L)	01/02/91	9.41		10.77	
TOT. PROTEINS	60-80 (G/L)	01/02/91	71.00		68.00	
ALBUMINE	50-65 (%)	01/02/91	51.80		49.50 <	
TOT. CHOLEST.	3.6-7 (MMOL/L)	01/02/91	6.48		7.85 >	
TRIGLYCERIDES	0.46-1.6 (MMOL/L)	01/02/91	2.83 >>		1.92 >	
GLOBULINS ALPHA 1	2-6 (%)	01/02/91	2.80		2.40	
GLOBULINS ALPHA 2	6-10 (%)	01/02/91	12.30 >		10.50 >	
GLOBULINS BETA	9-14 (%)	01/02/91	14.90 >		14.90 >	
GLOBULINS GAMMA	14-22 (%)	01/02/91	18.30		22.70 >	
TSH	0.25-5 (MU/L)	01/02/91	0.30			
T4	7.1-18.5 (NG/L)	01/02/91	15.00			

1739

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/2 Patient: 99/A Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Day 21		Day 42	
			10/04/91		04/05/91	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/02/91	13.50		15.30	
HT	35-45 (X)	01/02/91	40.00		47.00	>
RBC	4-5 (10 ⁶ /UL)	01/02/91	4.63		5.17	>
MBC	4000-10000 (/UL)	01/02/91	5800.00		8500.00	
MBC: N	50-70 (X)	01/02/91	52.00		59.00	
MBC: L	20-40 (X)	01/02/91	42.00	>	37.00	
MBC: E	0-3 (X)	01/02/91	2.00		1.00	
MBC: M	2-8 (X)	01/02/91	4.00		3.00	
MBC: B	0-2 (X)	01/02/91	0.00		0.00	
PLATELETS	150000-400000 (/UL)	01/02/91	205000		230000	
NA+	138-146 (MEQ/L)	01/02/91	142.00		140.00	
K+	3.8-5 (MEQ/L)	01/02/91	3.80		4.00	
CL-	95-105 (MEQ/L)	01/02/91	101.00		99.00	
Ca++	88-102 (MG/L)	01/02/91	93.50			
PO4--	25-50 (MG/L)	01/02/91	26.00			
SGOT	5-27 (UI/L)	01/02/91	11.00			
SGPT	5-32 (UI/L)	01/02/91	8.00			
GAMMA GT	5-35 (UI/L)	01/02/91	7.00			
LDH	120-320 (UI/L)	01/02/91	196.00			
ALK, PHOSPH.	30-90 (UI/L)	01/02/91	28.00	<		
GLUCOSE	0.8-1.05 (G/L)	01/02/91	1.42	>>		
UREA	0.15-0.45 (G/L)	01/02/91	0.16			
CREATININE	6-13 (MG/L)	01/02/91	11.70			
URIC ACID	30-70 (MG/L)	01/02/91	56.00			
TOT. PROTEINS	65-78 (G/L)	01/02/91	69.00		77.00	
ALBUMINE	57-65 (X)	01/02/91	56.00	<	44.60	<
TOT. CHOLEST.	1.5-2.5 (G/L)	01/02/91	1.47	<		
TRIGLYCERIDES	0.4-1.6 (G/L)	01/02/91	1.95	>		
GLOBULINS ALPHA 1	2-4 (X)	01/02/91	3.20		4.10	>
GLOBULINS ALPHA 2	6-10 (X)	01/02/91	9.50		13.00	>
GLOBULINS BETA	8-12 (X)	01/02/91	13.20	>	16.20	>>
GLOBULINS GAMMA	12-19 (X)	01/02/91	18.10		22.10	>
TSH	0.25-5 (MU/L)	01/02/91	1.60			
T4	7.1-18.5 (NG/L)	01/02/91	13.50			

1740

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/2 Patient: 104 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date
			Day 21
			04/06/91
			value (⊕)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/02/91	14.20
HT	35-45 (%)	01/02/91	45.00
RBC	4-5 (10 ⁶ /UL)	01/02/91	4.89
WBC	4000-10000 (/UL)	01/02/91	6100.00
WBC: N	50-70 (%)	01/02/91	51.00
WBC: L	20-40 (%)	01/02/91	44.00 >
WBC: E	0-3 (%)	01/02/91	0.00
WBC: M	2-8 (%)	01/02/91	5.00
WBC: B	0-2 (%)	01/02/91	0.00
PLATELETS	150000-400000 (/UL)	01/02/91	240000
NA+	138-146 (MEQ/L)	01/02/91	139.00
K+	3.8-5 (MEQ/L)	01/02/91	4.20
CL-	95-105 (MEQ/L)	01/02/91	98.00
Ca++	88-102 (MG/L)	01/02/91	93.70
PO4--	25-50 (MG/L)	01/02/91	39.00
SGOT	5-27 (UI/L)	01/02/91	13.00
SGPT	5-32 (UI/L)	01/02/91	6.00
GAMMA GT	5-35 (UI/L)	01/02/91	10.00
LDH	120-320 (UI/L)	01/02/91	287.00
ALK. PHOSPH.	30-90 (UI/L)	01/02/91	51.00
GLUCOSE	0.8-1.05 (G/L)	01/02/91	1.04
UREA	0.15-0.45 (G/L)	01/02/91	0.30
CREATININE	6-13 (MG/L)	01/02/91	11.00
URIC ACID	30-70 (MG/L)	01/02/91	63.00
TOT. BILIRUBIN	1.5-10 (MG/L)	01/02/91	3.90
TOT. PROTEINS	65-78 (G/L)	01/02/91	78.00
ALBUMINE	57-65 (%)	01/02/91	50.90 <
TOT. CHOLEST.	1.5-2.5 (G/L)	01/02/91	2.42
TRIGLYCERIDES	0.4-1.6 (G/L)	01/02/91	1.23
GLOBULINS ALPHA 1	2-4 (%)	01/02/91	2.30
GLOBULINS ALPHA 2	6-10 (%)	01/02/91	10.80 >
GLOBULINS BETA	8-12 (%)	01/02/91	12.10 >
GLOBULINS GAMMA	12-19 (%)	01/02/91	23.90 >
TSH	0.25-5 (MU/L)	01/02/91	0.72
T4	7.1-18.5 (NG/L)	01/02/91	11.70

1741

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/3 Patient: 97 Treatment: Placebo Sex: Male

			Visit number / Laboratory date	
			Screen	Day 42
			11/04/91	28/05/91
			value (⊕)	value (⊕)
Laboratory test	Range value	Range date		
HB	12-18 (G/DL)	01/03/91	15.20	16.00
HT	35-54 (%)	01/03/91	44.44	45.40
RBC	4-5.9 (10 ⁶ /UL)	01/03/91	5.00	4.93
MBC	4500-9999 (/UL)	01/03/91	13500.0 >>	10200.0 >
MBC: N	45-70 (%)	01/03/91	67.00	56.00
MBC: L	20-40 (%)	01/03/91	26.00	33.00
MBC: E	1-4 (%)	01/03/91	3.00	1.00
MBC: M	3-10 (%)	01/03/91	4.00	10.00
MBC: B	0-1 (%)	01/03/91	0.00	0.00
PLATELETS	200-400 (10 ³ /UL)	01/03/91	280.00	299.00
NA+	138-145 (MMOL/L)	01/03/91	139.00	138.00
K+	3.9-4.8 (MMOL/L)	01/03/91	4.50	4.00
CL-	98-107 (MMOL/L)	01/03/91	103.00	98.00
Ca++	88-104 (MG/L)	01/03/91	100.10	101.40
PO4--	25-45 (MG/L)	01/03/91	36.60	38.60
SGOT	2-38 (UI/L)	01/03/91	11.00	12.00
SGPT	5-41 (UI/L)	01/03/91	23.00	15.00
GAMMA GT	6-28 (UI/L)	01/03/91	14.00	11.00
LDH	140-330 (UI/L)	01/03/91	200.00	262.00
ALK. PHOSPH.	30-90 (UI/L)	01/03/91	51.00	41.00
GLUCOSE	0.7-1.1 (G/L)	01/03/91	1.10	1.05
UREA	0.2-0.45 (G/L)	01/03/91	0.29	0.29
CREATININE	6-12 (MG/L)	01/03/91	9.60	12.00
URIC ACID	25-65 (MG/L)	01/03/91	53.80	59.00
TOT BILIRUBIN	1.5-10 (MG/L)	01/03/91	6.10	5.60
TOT. PROTEINS	60-80 (G/L)	01/03/91	66.00	64.00
ALBUMINE	55-65 (%)	01/03/91	68.80 >>	63.90
TOT. CHOLEST.	1.4-2 (G/L)	01/03/91	2.79 >>	2.60 >
TRIGLYCERIDES	0.4-1.6 (G/L)	01/03/91	1.63 >	1.13
GLOBULINS ALPHA 1	1-4 (%)	01/03/91	3.20	3.00
GLOBULINS ALPHA 2	5-10 (%)	01/03/91	9.80	13.40 >>
GLOBULINS BETA	8-13 (%)	01/03/91	9.70	11.20
GLOBULINS GAMMA	12-20 (%)	01/03/91	8.50 <	8.50 <
TSH	0.2-2.9 (UUI/NL)	01/03/91	1.26	
T4	10-28 (PMOL/L)	01/03/91	15.30	

1742

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/3 Patient: 98 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 35	
			17/06/91		13/07/91		02/08/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/91	14.80		14.80		15.40	
HT	37-47 (X)	01/06/91	46.40		46.40		44.70	
RBC	4.1-5.3 (10 ⁶ /UL)	01/06/91	5.01		5.01		5.33 >	
MBC	4000-10000 (/UL)	01/06/91	5300.00		5300.00		5900.00	
MBC: N	60-70 (X)	01/06/91	53.00 <		53.00 <		63.00	
MBC: L	25-50 (X)	01/06/91	43.00		43.00		34.00	
MBC: E	0-3 (X)	01/06/91	1.00		1.00		0.00	
MBC: M	0-10 (X)	01/06/91	3.00		3.00		3.00	
MBC: B	0-3 (X)	01/06/91	0.00		0.00		0.00	
PLATELETS	200000-500000 (/UL)	01/06/91	242000				278000	
NA+	130-145 (MEQ/L)	01/06/91	140.00		142.00		143.00	
K+	3.6-4.8 (MEQ/L)	01/06/91	4.80		4.60		4.80	
CL-	95-110 (MEQ/L)	01/06/91	100.00		103.00		101.00	
Ca++	85-105 (MG/L)	01/06/91	91.00		96.00		95.00	
PO4--	25-50 (MG/L)	01/06/91	46.00		35.00		40.00	
SGOT	5-30 (UI/L)	01/06/91	36.00 >		17.00		19.00	
SGPT	7-32 (UI/L)	01/06/91	33.00 >		18.00		15.00	
GAMMA GT	7-32 (UI/L)	01/06/91			18.00		12.00	
LDH	190-380 (UI/L)	01/06/91	284.00		249.00		261.00	
ALK. PHOSPH.	30-125 (UI/L)	01/06/91			60.00		56.00	
GLUCOSE	0.75-1.1 (G/L)	01/06/91	0.86		0.94		0.90	
UREA	0.1-0.5 (G/L)	01/06/91	0.39		0.22		0.25	
CREATININE	5-12 (MG/L)	01/06/91	11.00		11.00		12.00	
URIC ACID	25-60 (MG/L)	01/06/91	35.00		38.00		42.00	
TOT BILIRUBIN	2-12 (MG/L)	01/06/91	3.00		3.00		3.00	
DIR BILIRUBIN	0-3 (MG/L)	01/06/91	2.00		2.00		2.00	
TOT. PROTEINS	65-80 (G/L)	01/06/91	76.00		67.00		60.00 <	
ALBUMINE	37-42 (G/L)	01/06/91	44.00 >		39.40		34.00 <	
TOT. CHOLEST.	1.5-2.4 (G/L)	01/06/91	2.27		2.00		1.98	
TRIGLYCERIDES	0.5-1.5 (G/L)	01/06/91	0.69		0.65		0.64	
GLOBULINS ALPHA 1	1-3 (G/L)	01/06/91	2.30		2.00		2.10	
GLOBULINS ALPHA 2	1-3 (G/L)	01/06/91	7.40 >>		6.40 >>		5.90 >>	
GLOBULINS BETA	5-8 (G/L)	01/06/91	10.90 >>		9.20 >		8.80 >	
GLOBULINS GAMMA	8-12 (G/L)	01/06/91	11.40		10.00		9.20	

1743

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/3 Patient: 99 Treatment: Placebo Sex: Female

			Visit number / Laboratory date
			Screen
			07/08/91
			value (⊕)
Laboratory test	Range value	Range date	
HB	12-17 (G/DL)	01/08/91	12.70
HT	35-54 (%)	01/08/91	35.90
RBC	4000000-5500000 (/UL)	01/08/91	4050000
WBC	4000-9000 (/UL)	01/08/91	7300.00
WBC: N	60-70 (%)	01/08/91	58.00 <
WBC: L	25-50 (%)	01/08/91	33.00
WBC: E	0-3 (%)	01/08/91	3.00
WBC: M	0-10 (%)	01/08/91	6.00
WBC: B	0-3 (%)	01/08/91	0.00
PLATELETS	200000-400000 (/UL)	01/08/91	355000
NA+	137-146 (MMOL/L)	01/08/91	140.00
K+	3.8-5.2 (MMOL/L)	01/08/91	3.90
CL-	95-106 (MMOL/L)	01/08/91	102.00
Ca++	85-101 (MG/L)	01/08/91	99.00
PO4--	25-42 (MG/L)	01/08/91	37.00
SGOT	0-25 (UI/L)	01/08/91	10.00
SGPT	0-29 (UI/L)	01/08/91	7.00
GAMMA GT	7-34 (UI/L)	01/08/91	11.00
LDH	140-280 (UI/L)	01/08/91	181.00
ALK. PHOSPH.	30-100 (UI/L)	01/08/91	80.00
GLUCOSE	0.7-1.1 (G/L)	01/08/91	0.92
UREA	0.15-0.5 (G/L)	01/08/91	0.35
CREATININE	5-12 (MG/L)	01/08/91	7.00
URIC ACID	24-57 (MG/L)	01/08/91	22.00 <
TOT BILIRUBIN	1.5-10 (MG/L)	01/08/91	4.60
TOT. PROTEINS	65-87 (G/L)	01/08/91	65.00
ALBUMINE	57-65 (%)	01/08/91	64.40
TOT. CHOLEST.	1.2-2 (G/L)	01/08/91	2.19 >
TRIGLYCERIDES	0.4-1.5 (G/L)	01/08/91	0.81
GLOBULINS ALPHA 1	2-4 (%)	01/08/91	3.00
GLOBULINS ALPHA 2	6-10 (%)	01/08/91	7.70
GLOBULINS BETA	8-12 (%)	01/08/91	11.40
GLOBULINS GAMMA	12-19 (%)	01/08/91	13.50
TSH	0.3-5 (UUI/ML)	01/08/91	3.10
T4	6.8-17.6 (PG/ML)	01/08/91	12.77

1744

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/3 Patient: 100 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			22/11/91		08/01/92	
			value	(†)	value	(†)
Laboratory test	Range value	Range date				
HB	12-16 (G/100HL)	20/11/91	14.00		13.50	
HT	37-47 (X)	20/11/91	41.70		40.90	
RBC	4.1-5.3 (10 ⁶ /MM ³)	20/11/91	4.59		4.51	
WBC	4000-10000 (/MM ³)	20/11/91	6300.00		5900.00	
WBC: N	45-74 (X)	20/11/91	44.00	<	47.00	
WBC: L	16-45 (X)	20/11/91	46.00	>	42.00	
WBC: E	0-7 (X)	20/11/91	5.00		6.00	
WBC: M	4-10 (X)	20/11/91	5.00		5.00	
WBC: B	0-2 (X)	20/11/91	0.00		0.00	
PLATELETS	200-500 (10 ³ /MM ³)	20/11/91	280.00		263.00	
NA+	135-145 (MEQ/L)	20/11/91	138.00		139.00	
K+	3.7-5.2 (MEQ/L)	20/11/91	3.40	<	3.80	
CL-	100-107 (MEQ/L)	20/11/91	101.00		101.00	
Ca++	90-105 (MG/L)	20/11/91	92.00		94.00	
PO4--	25-45 (MG/L)	20/11/91	33.00		38.00	
SGOT	2-25 (UI/L)	20/11/91	17.00		14.00	
SGPT	5-35 (UI/L)	20/11/91	10.00		9.00	
GAMMA GT	7-35 (UI/L)	20/11/91	8.00		9.00	
LDH	190-380 (UI/L)	20/11/91	341.00		332.00	
ALK. PHOSPH.	30-100 (UI/L)	20/11/91	65.00		50.00	
GLUCOSE	0.7-1.1 (G/L)	20/11/91	0.84		0.99	
UREA	0.2-0.45 (G/L)	20/11/91	0.27		0.25	
CREATININE	5-12 (MG/L)	20/11/91	8.90		6.30	
URIC ACID	30-70 (MG/L)	20/11/91	39.00		48.00	
TOT. BILIRUBIN	1.5-10 (MG/L)	20/11/91	7.30		3.10	
TOT. PROTEINS	60-80 (G/L)	20/11/91	70.00		72.00	
ALBUMINE	37-42 (G/L)	20/11/91	38.90		37.80	
TOT. CHOLEST.	1.5-2.5 (G/L)	20/11/91	2.49		2.93 >	
TRIGLYCERIDES	0.4-1.5 (G/L)	20/11/91			0.57	
GLOBULINS ALPHA 1	1-3 (G/L)	20/11/91	2.50		1.50	
GLOBULINS ALPHA 2	4-7 (G/L)	20/11/91	7.20	>	6.40	
GLOBULINS BETA	5-8 (G/L)	20/11/91	8.50	>	10.50 >>	
GLOBULINS GAMMA	8-12 (G/L)	20/11/91	12.70	>	15.60 >	
TSH	0.2-4 (UUI/ML)	20/11/91	0.94			
T4	7-17 (PG/ML)	20/11/91	12.50			

1745

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/3 Patient: 101 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 42
			16/03/92	27/04/92
			value (c)	value (c)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	15/03/91	15.30	14.40
HT	37-47 (%)	15/03/91	44.60	41.40
RBC	4.1-5.3 (10 ⁶ /UL)	15/03/91	4.73	4.51
WBC	4000-10000 (/UL)	15/03/91	5300.00	4700.00
WBC: N	60-70 (%)	15/03/91	51.00	54.00
WBC: L	25-50 (%)	15/03/91	41.00	38.00
WBC: E	0-3 (%)	15/03/91	1.00	0.00
WBC: M	0-10 (%)	15/03/91	6.00	7.00
WBC: B	0-3 (%)	15/03/91	1.00	1.00
PLATELETS	200-500 (10 ³ /MM3)	15/03/91	232.00	221.00
NA+	130-145 (MEQ/L)	15/03/91	141.00	138.00
K+	3.6-4.8 (MEQ/L)	15/03/91	4.00	3.90
CL-	95-110 (MEQ/L)	15/03/91	101.00	100.00
Ca++	85-105 (MG/L)	15/03/91	92.00	90.00
PO4--	25-50 (MG/L)	15/03/91	31.00	33.00
SGOT	5-30 (UI/L)	15/03/91	29.00	62.00
SGPT	7-32 (UI/L)	15/03/91	37.00	73.00
GAMMA GT	7-35 (UI/ML)	15/03/91	59.00	63.00
LDH	190-380 (UI/L)	15/03/91	297.00	346.00
ALK. PHOSPH.	30-100 (UI/L)	15/03/91	76.00	97.00
GLUCOSE	0.75-1.1 (G/L)	15/03/91	1.11	1.05
UREA	0.1-0.5 (G/L)	15/03/91	0.37	0.36
CREATININE	5-12 (MG/L)	15/03/91	10.00	8.60
URIC ACID	25-60 (MG/L)	15/03/91	60.00	57.00
TOT BILIRUBIN	2-12 (MG/L)	15/03/91	14.20	12.80
TOT. PROTEINS	65-80 (G/L)	15/03/91	68.00	68.00
ALBUMINE	37-42 (G/L)	15/03/91	39.90	42.70
TOT. CHOLEST.	1.5-2.4 (G/L)	15/03/91	1.81	1.84
TRIGLYCERIDES	0.5-1.5 (G/L)	15/03/91	0.79	0.65
GLOBULINS ALPHA 1	1-3 (G/L)	15/03/91	2.20	2.30
GLOBULINS ALPHA 2	4-7 (G/L)	15/03/91	4.80	4.10
GLOBULINS BETA	5-8 (G/L)	15/03/91	9.70	8.50
GLOBULINS GAMMA	8-12 (G/L)	15/03/91	11.20	10.10

1746

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/4 Patient: 109 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/06/91		27/06/91		20/08/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/05/91	13.50		13.30		14.00	
HT	36-52 (X)	01/05/91	40.70		40.10		41.30	
RBC	4.5-5.5 (10 ¹² /L)	01/05/91	4.17 <		4.15 <		4.19 <	
WBC	4-10 (10 ⁹ /L)	01/05/91	6.10		6.00		8.00	
WBC: N	2-7.5 (10 ⁹ /L)	01/05/91	2.98		3.36		4.96	
WBC: L	1.5-4 (10 ⁹ /L)	01/05/91	2.56		2.16		2.48	
WBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.24		0.18		0.16	
WBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.30		0.36		0.32	
WBC: B	0.04-0.5 (10 ⁹ /L)	01/05/91	0.00 <		0.00 <		0.08	
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	225.00		204.00		185.00 <	
NA+	136-144 (MMOL/L)	01/05/91	141.00		141.00		142.00	
K+	3.6-5 (MMOL/L)	01/05/91	4.60		4.40		4.00	
CL-	95-105 (MMOL/L)	01/05/91	106.00 >		108.00 >		109.00 >	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.51		2.43		2.37	
PO4--	0.8-1.4 (MMOL/L)	01/05/91			1.42 >		1.11	
SGOT	5-25 (U/L)	01/05/91	11.00		12.00		10.00	
SGPT	5-35 (U/L)	01/05/91	11.00		11.00		12.00	
GAMMA GT	5-25 (U/L)	01/05/91	9.00		8.00		10.00	
LDH	120-320 (U/L)	01/05/91	241.00		224.00		192.00	
ALK. PHOSPH.	35-85 (U/L)	01/05/91	44.00		40.00		42.00	
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	5.80		4.80		4.70	
UREA	2.8-7.4 (MMOL/L)	01/05/91	4.60		5.20		4.10	
CREATININE	55-100 (UMOL/L)	01/05/91	81.00		69.00		75.00	
URIC ACID	180-360 (UMOL/L)	01/05/91	242.00		255.00		256.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	6.00		3.00		3.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/05/91			1.00			
TOT. PROTEINS	63-80 (G/L)	01/05/91	70.00		67.00		68.00	
ALBUMINE	38-50 (G/L)	01/05/91	44.70		43.60		44.50	
TOT. CHOLEST.	4-7 (MMOL/L)	01/05/91	4.61		4.84		5.06	
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	0.58		0.53		0.66	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.90		2.00		2.00	
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	6.00		5.60		5.40	
GLOBULINS BETA	6-12 (G/L)	01/05/91	7.30		7.20		7.10	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	9.00		8.60		8.90	
TSH	0.3-5 (UU/ML)	01/05/91	3.86					
T4	9.2-22.7 (PHOL/ML)	01/05/91	16.00					

1747

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/4 Patient: 110 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/06/91		04/07/91		26/07/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/05/91	13.30		14.00		14.90	
HT	36-52 (x)	01/05/91	39.60		41.60		43.60	
RBC	4-5.8 (10 ¹² /L)	01/05/91	4.51		4.71		4.99	
HBC	4-10 (10 ⁹ /L)	01/05/91	5.20		4.40		4.70	
HBC: N	2-7.5 (10 ⁹ /L)	01/05/91	2.54		2.28		2.06	
HBC: L	1.5-4 (10 ⁹ /L)	01/05/91	2.08		1.67		2.11	
HBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.15		0.13		0.14	
HBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.36		0.26		0.32	
HBC: B	0.01-0.1 (10 ⁹ /L)	01/05/91	0.05		0.04		0.04	
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	244.00		295.00		332.00	
NA+	136-144 (MMOL/L)	01/05/91	142.00		140.00		142.00	
K+	3.6-5 (MMOL/L)	01/05/91	4.40		3.90		4.20	
CL-	95-105 (MMOL/L)	01/05/91	100.00		99.00		99.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.54		2.46		2.52	
PO4--	0.8-1.4 (MMOL/L)	01/05/91			1.05		1.32	
SGOT	5-25 (U/L)	01/05/91	17.00		14.00		32.00 >	
SGPT	5-35 (U/L)	01/05/91	26.00		28.00		62.00 >	
GAMMA GT	5-25 (U/L)	01/05/91	85.00 >>		87.00 >>		195.00 >>	
LDH	120-320 (U/L)	01/05/91	186.00		172.00		231.00	
ALK. PHOSPH.	50-200 (U/L)	01/05/91	87.00		73.00		74.00	
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	5.30		5.20		4.90	
UREA	3.2-7.7 (MMOL/L)	01/05/91	4.40		3.10 <		5.10	
CREATININE	63-142 (UMOL/L)	01/05/91	68.00		64.00		68.00	
URIC ACID	240-420 (UMOL/L)	01/05/91	330.00		472.00 >		551.00 >>	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	5.00		4.00		4.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/05/91	2.00				1.00	
TOT. PROTEINS	63-80 (G/L)	01/05/91	63.00		63.00		66.00	
ALBUMINE	38-50 (G/L)	01/05/91	37.40 <		38.80		41.20	
TOT. CHOLEST.	3.5-5.2 (MMOL/L)	01/05/91	7.04 >>				9.01 >>	
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	2.77 >>				2.31 >>	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.70		2.40		2.50	
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	6.60		5.40		5.20	
GLOBULINS BETA	6-12 (G/L)	01/05/91	8.90		9.10		4.80 <	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	7.40		7.40		7.50	
TSH	0.3-5 (UU/ML)	01/05/91	1.29					
T4	9.2-22.7 (PMOL/ML)	01/05/91	10.90					

1748

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/4 Patient: 111 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/06/91		24/07/91		14/08/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/05/91	16.10		15.00		15.10	
HT	36-52 (X)	01/05/91	48.70		45.00		44.90	
RBC	4-5.8 (10 ¹² /L)	01/05/91	5.65		5.19		5.16	
MBC	4-10 (10 ⁹ /L)	01/05/91	9.60		8.80		8.20	
MBC: N	2-7.5 (10 ⁹ /L)	01/05/91	7.00		5.89		5.33	
MBC: L	1.5-4 (10 ⁹ /L)	01/05/91	1.92		2.20		2.21	
MBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.19		0.25		0.24	
MBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.38		0.35		0.32	
MBC: B	0.01-0.1 (10 ⁹ /L)	01/05/91	0.09		0.08		0.08	
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	311.00		307.00		291.00	
NA+	136-144 (MMOL/L)	01/05/91	141.00		141.00		144.00	
K+	3.6-5 (MMOL/L)	01/05/91	4.00		4.40		4.40	
CL-	95-105 (MMOL/L)	01/05/91	102.00		101.00		105.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.53		2.49		2.51	
PO4--	0.8-1.4 (MMOL/L)	01/05/91	1.25		1.18		1.09	
SGOT	5-25 (U/L)	01/05/91	12.00		7.00		10.00	
SGPT	5-35 (U/L)	01/05/91	12.00		7.00		8.00	
GAMMA GT	5-25 (U/L)	01/05/91	16.00		12.00		11.00	
LDH	120-320 (U/L)	01/05/91	197.00		144.00		151.00	
ALK. PHOSPH.	50-200 (U/L)	01/05/91	63.00		51.00		49.00 <	
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	4.30		5.30		4.80	
UREA	3.2-7.7 (MMOL/L)	01/05/91	4.80		6.80		7.80 >	
CREATININE	63-142 (UMOL/L)	01/05/91	77.00		83.00		84.00	
URIC ACID	240-420 (UMOL/L)	01/05/91	302.00		285.00		290.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	14.00		10.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/05/91			2.00			
TOT. PROTEINS	63-80 (G/L)	01/05/91	78.00		67.00		69.00	
ALBUMINE	38-50 (G/L)	01/05/91	52.40	>	44.20		44.00	
TOT. CHOLEST.	3.5-5.2 (MMOL/L)	01/05/91	8.65	>>	7.78	>>	8.15 >>	
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	1.46		1.25		0.53	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	1.70		1.60		1.70	
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	6.40		5.20		6.10	
GLOBULINS BETA	6-12 (G/L)	01/05/91	8.70		4.40	<	9.70	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	8.70		7.60		7.70	
TSH	0.3-5 (UU/ML)	01/05/91	1.11					
T4	9.2-22.7 (PMOL/ML)	01/05/91	13.20					

1749

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/4 Patient: 112 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/07/91		31/07/91		20/08/91	
			value	(⊖)	value	(⊖)	value	(⊖)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/05/91	14.40		15.60		15.20	
HT	36-52 (cm)	01/05/91	42.60		46.90		45.40	
RBC	4-5.8 (10 ¹² /L)	01/05/91	4.73		5.20		5.13	
WBC	4-10 (10 ⁹ /L)	01/05/91	6.20		6.40		5.70	
WBC: N	2-7.5 (10 ⁹ /L)	01/05/91	2.66		3.71		3.07	
WBC: L	1.5-4 (10 ⁹ /L)	01/05/91	2.85		2.17		2.10	
WBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.24		0.19		0.17	
WBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.37		0.32		0.28	
WBC: B	0.01-0.1 (10 ⁹ /L)	01/05/91	0.06		0.00 <		0.05	
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	395.00		386.00		358.00	
NA+	136-144 (MMOL/L)	01/05/91	142.00		142.00		143.00	
K+	3.6-5 (MMOL/L)	01/05/91	4.00		3.60		3.70	
CL-	95-105 (MMOL/L)	01/05/91	103.00		107.00 >		104.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.47		2.51		2.56	
PO4--	0.8-1.4 (MMOL/L)	01/05/91	1.83 >>		1.05		1.28	
SGOT	5-25 (U/L)	01/05/91	14.00		10.00		12.00	
SGPT	5-35 (U/L)	01/05/91	24.00		20.00		17.00	
GAMMA GT	5-25 (U/L)	01/05/91	16.00		14.00		11.00	
LDH	120-320 (U/L)	01/05/91			153.00		161.00	
ALK. PHOSPH.	50-200 (U/L)	01/05/91	49.00 <		58.00		59.00	
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	5.10		5.00		4.60	
UREA	3.2-7.7 (MMOL/L)	01/05/91	3.70		4.50		3.40	
CREATININE	63-112 (UMOL/L)	01/05/91	67.00		85.00		89.00	
URIC ACID	240-420 (UMOL/L)	01/05/91	300.00		358.00		350.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	9.00		12.00		6.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/05/91	1.00					
TOT. PROTEINS	63-80 (G/L)	01/05/91	73.00		77.00		83.00 >	
ALBUMINE	38-50 (G/L)	01/05/91	46.90		48.90		51.10 >	
TOT. CHOLEST.	3.5-5.2 (MMOL/L)	01/05/91	5.76 >		5.71 >		6.17 >	
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	0.96		1.03		1.22	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.00		1.90		2.20	
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	5.00		5.20		5.70	
GLOBULINS BETA	6-12 (G/L)	01/05/91	4.70 <		8.90		9.10	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	10.30		12.20		10.90	
TSH	0.3-5 (UU/ML)	01/05/91	1.20					
T4	9.2-22.7 (PMOL/ML)	01/05/91	18.50					

1750

(⊖) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/4 Patient: 113 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/08/91		23/09/91		11/10/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/05/91	14.00		13.50		13.80	
HT	36-52 (X)	01/05/91	40.80		39.20		39.40	
RBC	4-5.8 (10 ¹² /L)	01/05/91	4.71		4.53		4.56	
WBC	4-10 (10 ⁹ /L)	01/05/91	8.20		6.60		7.50	
WBC: N	2-7.5 (10 ⁹ /L)	01/05/91	4.67		3.89		4.42	
WBC: L	1.5-4 (10 ⁹ /L)	01/05/91	2.54		1.84		2.17	
WBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.41		0.33		0.45	
WBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.49		0.46		0.37	
WBC: B	0.01-0.1 (10 ⁹ /L)	01/05/91	0.08		0.06		0.07	
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	253.00		265.00		242.00	
NA+	136-144 (MMOL/L)	01/05/91	142.00		140.00		142.00	
K+	3.6-5 (MMOL/L)	01/05/91	4.10		3.50 <		4.00	
CL-	95-105 (MMOL/L)	01/05/91	105.00		102.00		102.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.46		2.52		2.47	
PO4--	0.8-1.4 (MMOL/L)	01/05/91	1.37		1.36		1.41 >	
SGOT	5-25 (U/L)	01/05/91	10.00		12.00		9.00	
SGPT	5-35 (U/L)	01/05/91	19.00		18.00		17.00	
GAMMA GT	5-25 (U/L)	01/05/91	11.00		12.00		11.00	
LDH	120-320 (U/L)	01/05/91	135.00		157.00		134.00	
ALK. PHOSPH.	50-200 (U/L)	01/05/91	44.00 <		46.00 <		45.00 <	
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	5.60		5.40		5.50	
UREA	3.2-7.7 (MMOL/L)	01/05/91	4.30		4.40		4.10	
CREATININE	63-112 (UMOL/L)	01/05/91	84.00		81.00		87.00	
URIC ACID	240-420 (UMOL/L)	01/05/91	312.00		509.00 >		447.00 >	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	11.00		16.00			
TOT. PROTEINS	63-80 (G/L)	01/05/91	66.00		64.00		66.00	
ALBUMINE	38-50 (G/L)	01/05/91	43.50		44.50		46.50	
TOT. CHOLEST.	3.5-5.2 (MMOL/L)	01/05/91	3.12 <		3.37 <		3.60	
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	0.69		0.51		0.45 <	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.20		1.80		1.70	
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	5.10		3.90 <		3.80 <	
GLOBULINS BETA	6-12 (G/L)	01/05/91	6.70		6.10		5.70 <	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	8.50		7.80		8.40	
TSH	0.3-5 (UU/ML)	01/05/91	1.45					
T4	9,2-22,7 (PMOL/ML)	01/05/91	18.60					

1751

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/4 Patient: 114 Treatment: Placebo Sex: Female

			Visit number / Laboratory date							
			Screen		Day 0		Day 21		Day 42	
			07/11/91		07/11/91		10/12/91		31/12/91	
			value	(€)	value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date								
HB	11.5-17 (G/DL)	01/05/91	13.50		13.10		13.00		13.30	
HT	36-52 (%)	01/05/91	39.10		39.00		37.50		38.20	
RBC	4.5-5.5 (10 ¹² /L)	01/05/91	4.41 <		4.40 <		4.26 <		4.35 <	
WBC	4-10 (10 ⁹ /L)	01/05/91	3.10 <		4.58		3.80 <		2.90 <<	
WBC: N	2-7.5 (10 ⁹ /L)	01/05/91	1.05 <<		1.79 <		1.52 <		1.10 <<	
WBC: L	1.5-4 (10 ⁹ /L)	01/05/91	1.64		2.34		1.78		1.30 <	
WBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.18		0.14		0.22		0.23	
WBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.18 <		0.27		0.22		0.23	
WBC: B	0.04-0.5 (10 ⁹ /L)	01/05/91	0.03 <		0.05		0.03 <		0.02 <	
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	241.00				232.00		247.00	
NA+	136-144 (MMOL/L)	01/05/91	141.00				141.00		140.00	
K+	3.6-5 (MMOL/L)	01/05/91	3.80				3.50 <		3.40 <	
CL-	95-105 (MMOL/L)	01/05/91	102.00				102.00		102.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.39				2.38		2.34	
PO4--	0.8-1.4 (MMOL/L)	01/05/91	0.90				0.91		0.84	
SGOT	5-25 (U/L)	01/05/91	12.00				11.00		11.00	
SGPT	5-35 (U/L)	01/05/91	11.00				14.00		13.00	
GAMMA GT	5-25 (U/L)	01/05/91	16.00				14.00		13.00	
LDH	120-320 (U/L)	01/05/91	202.00				190.00		200.00	
ALK. PHOSPH.	35-85 (U/L)	01/05/91	62.00				59.00		60.00	
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	6.50 >				5.80		5.40	
UREA	2.8-7.4 (MMOL/L)	01/05/91	3.50				4.20		3.50	
CREATININE	55-100 (UMOL/L)	01/05/91	65.00				68.00		62.00	
URIC ACID	180-360 (UMOL/L)	01/05/91	176.00 <				189.00		189.00	
TOT. BILIRUBIN	3-20 (UMOL/L)	01/05/91	9.00				8.00		7.00	
TOT. PROTEINS	63-80 (G/L)	01/05/91	75.00				72.00		73.00	
ALBUMINE	38-50 (G/L)	01/05/91	45.60				37.90 <			
TOT. CHOLEST.	4-7 (MMOL/L)	01/05/91	7.21 >				5.70		5.55	
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	0.87				1.02		0.73	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.10				2.60		2.30	
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	5.30				5.00		5.00	
GLOBULINS BETA	6-12 (G/L)	01/05/91	8.30				8.40		8.30	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	13.80				14.70		13.80	
TSH	0.3-5 (UU/ML)	01/05/91	0.95							
T4	9.2-22.7 (PMOL/ML)	01/05/91	12.60							

1752

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/4 Patient: 175 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/02/92		04/03/92		25/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/05/91	11.90		12.30		11.80	
HT	36-52 (%)	01/05/91	34.70 <		36.80		36.10	
RBC	4.5-5.5 (10 ¹² /L)	01/05/91	3.97 <		4.19 <		4.07 <	
HBC	4-10 (10 ⁹ /L)	01/05/91	7.90		8.00		6.10	
HBC: N	2-7.5 (10 ⁹ /L)	01/05/91	4.66		5.28		3.60	
HBC: L	1.5-4 (10 ⁹ /L)	01/05/91	2.60		2.08		1.83	
HBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.15		0.24		0.24	
HBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.39		0.32		0.31	
HBC: B	0.04-0.5 (10 ⁹ /L)	01/05/91	0.07		0.08		0.12	
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	280.00		286.00		243.00	
NA+	136-144 (MMOL/L)	01/05/91	142.00		140.00		140.00	
K+	3.6-5 (MMOL/L)	01/05/91	3.80		4.00		3.90	
CL-	95-105 (MMOL/L)	01/05/91	101.00		99.00		98.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.47		2.42		2.42	
PO4--	0.8-1.4 (MMOL/L)	01/05/91	1.39		1.35		1.21	
SGOT	5-25 (U/L)	01/05/91	7.00		11.00		14.00	
SGPT	5-35 (U/L)	01/05/91	9.00		15.00		19.00	
GAMMA GT	5-25 (U/L)	01/05/91	19.00		15.00		13.00	
LDH	120-320 (U/L)	01/05/91	218.00				214.00	
ALK. PHOSPH.	35-85 (U/L)	01/05/91	61.00		62.00		72.00	
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	5.00		4.50		4.30	
UREA	2.8-7.4 (MMOL/L)	01/05/91	3.60		7.40		4.80	
CREATININE	55-100 (UMOL/L)	01/05/91	76.00		82.00		73.00	
URIC ACID	180-360 (UMOL/L)	01/05/91	249.00		375.00 >		336.00	
TOT. BILIRUBIN	3-20 (UMOL/L)	01/05/91	13.00		7.00		8.00	
TOT. PROTEINS	63-80 (G/L)	01/05/91	63.00		68.00		69.00	
ALBUMINE	38-50 (G/L)	01/05/91	41.50		45.20		46.60	
TOT. CHOLEST.	4-7 (MMOL/L)	01/05/91	6.90		8.39 >		7.54 >	
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	1.36		1.94 >		1.39	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.10		2.20		2.20	
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	5.00		4.70		5.00	
GLOBULINS BETA	6-12 (G/L)	01/05/91	7.30		8.20		7.90	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	7.00		7.70		7.40	
TSH	0.3-5 (UU/ML)	01/05/91	1.35					
T4	9.2-22.7 (PMOL/ML)	01/05/91	14.20					

1753

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/4 Patient: 176 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 28	
			13/03/92		06/04/92		09/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/03/92	13.30		14.50		10.70 <	
HT	36-52 (X)	01/03/92	39.80		44.00		33.00 <	
RBC	4.5-5.5 (10 ¹² /L)	01/03/92	4.41 <		4.80		3.57 <<	
WBC	4-10 (10 ⁹ /L)	01/03/92	4.70		8.40		7.60	
WBC: N	2-7.5 (10 ⁹ /L)	01/03/92	2.40		6.55			
	45-74 (X)	08/04/92					77.20 >	
WBC: L	1.5-4 (10 ⁹ /L)	01/03/92	1.74		1.26 <			
	16-45 (X)	08/04/92					15.20 <	
WBC: E	0.04-0.5 (10 ⁹ /L)	01/03/92	0.19		0.08			
	0-7 (X)	08/04/92					0.70	
WBC: M	0.2-1 (10 ⁹ /L)	01/03/92	0.33		0.42			
	4-10 (X)	08/04/92					6.60	
WBC: B	0.04-0.5 (10 ⁹ /L)	01/03/92	0.05		0.08			
	0-2 (X)	08/04/92					0.40	
PLATELETS	200-400 (10 ⁹ /L)	01/03/92	251.00		288.00		205.00	
NA+	136-144 (MMOL/L)	01/03/92	141.00		146.00 >		146.00	
K+	3.6-5 (MMOL/L)	01/03/92	3.90		3.30 <		3.60	
CL-	95-105 (MMOL/L)	01/03/92	102.00		107.00 >		107.00 >	
Ca++	2.15-2.6 (MMOL/L)	01/03/92	2.32		2.46		2.12 <	
PO4--	0.8-1.4 (MMOL/L)	01/03/92	1.38		1.23			
SGOT	5-25 (U/L)	01/03/92	8.00		7.00		28.00 >	
SGPT	5-35 (U/L)	01/03/92	11.00		9.00		15.00	
GAMMA GT	5-25 (U/L)	01/03/92	12.00		13.00			
LDH	120-320 (U/L)	01/03/92	181.00		196.00			
ALK. PHOSPH.	35-85 (U/L)	01/03/92	34.00 <		37.00			
GLUCOSE	3.9-5.8 (MMOL/L)	01/03/92	4.70		5.10			
UREA	2.8-7.4 (MMOL/L)	01/03/92	4.30		2.70 <		2.50 <	
CREATININE	55-100 (UMOL/L)	01/03/92	84.00		81.00		59.00	
URIC ACID	180-360 (UMOL/L)	01/03/92	199.00		222.00		171.00 <	
TOT. BILIRUBIN	3-20 (UMOL/L)	01/03/92	3.00		8.00			
TOT. PROTEINS	63-80 (G/L)	01/03/92	63.00		73.00		60.00 <	
ALBUMINE	38-50 (G/L)	01/03/92	40.40		47.20			
TOT. CHOLEST.	4-7 (MMOL/L)	01/03/92	5.70		6.88			
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/03/92	0.75		0.47 <			
GLOBULINS ALPHA 1	1-4 (G/L)	01/03/92	2.10		2.30			
GLOBULINS ALPHA 2	4-9 (G/L)	01/03/92	4.20		5.50			
GLOBULINS BETA	6-12 (G/L)	01/03/92	6.20		6.90			
GLOBULINS GAMMA	7-15 (G/L)	01/03/92	10.10		11.10			
TSH	0.3-5 (UU/ML)	01/03/92	1.37					
T4	9.2-22.7 (PNOL/ML)	01/03/92	16.50					

1754

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/4 Patient: 177 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			22/04/92		27/05/92	
			value	(†)	value	(†)
Laboratory test	Range value	Range date				
HB	11.5-17 (G/DL)	01/05/91	12.80		13.00	
HT	36-52 (X)	01/05/91	38.60		39.60	
RBC	4.5-5.5 (10 ¹² /L)	01/05/91	4.15	<	4.32	<
WBC	4-10 (10 ⁹ /L)	01/05/91	5.50		5.20	
WBC: N	2-7.5 (10 ⁹ /L)	01/05/91	3.08		3.02	
WBC: L	1.5-4 (10 ⁹ /L)	01/05/91	2.09		1.72	
WBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.06		0.00	<
WBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.22		0.47	
WBC: B	0.04-0.5 (10 ⁹ /L)	01/05/91	0.06		0.00	<
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	302.00		418.00	>
NA+	136-144 (MMOL/L)	01/05/91	144.00		143.00	
K+	3.6-5 (MMOL/L)	01/05/91	3.80		4.20	
CL-	95-105 (MMOL/L)	01/05/91	103.00		100.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.45		2.53	
PO4--	0.8-1.4 (MMOL/L)	01/05/91	1.29			
SGOT	5-25 (U/L)	01/05/91	11.00			
SGPT	5-35 (U/L)	01/05/91	25.00			
GAMMA GT	5-25 (U/L)	01/05/91	22.00			
LDH	120-320 (U/L)	01/05/91	193.00			
ALK. PHOSPH.	35-85 (U/L)	01/05/91	65.00			
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	5.80		5.60	
UREA	2.8-7.4 (MMOL/L)	01/05/91	4.10		2.50	<
CREATININE	55-100 (UMOL/L)	01/05/91	63.00		64.00	
URIC ACID	180-360 (UMOL/L)	01/05/91	289.00			
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	4.00			
TOT. PROTEINS	63-80 (G/L)	01/05/91	75.00			
ALBUMINE	38-50 (G/L)	01/05/91	45.00			
TOT. CHOLEST.	4-7 (MMOL/L)	01/05/91	7.18	>		
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	0.70			
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.20			
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	5.60			
GLOBULINS BETA	6-12 (G/L)	01/05/91	9.10			
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	13.10			
TSH	0.3-5 (UU/ML)	01/05/91	1.30			
T4	9.2-22.7 (PMOL/ML)	01/05/91	17.60			

1755

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 4/4 Patient: 178 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/04/92		18/05/92		09/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/05/91	11.20	<	13.70			
HT	36-52 (%)	01/05/91	33.10	<	41.70			
RBC	4.5-5.5 (10 ¹² /L)	01/05/91	3.15	<<	4.00	<		
HBC	4-10 (10 ⁹ /L)	01/05/91	3.80	<	4.70			
HBC: N	2-7.5 (10 ⁹ /L)	01/05/91	2.13		3.15			
HBC: L	1.5-4 (10 ⁹ /L)	01/05/91	1.25	<	1.18	<		
HBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.19		0.14			
HBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.19	<	0.24			
HBC: B	0.04-0.5 (10 ⁹ /L)	01/05/91	0.04		0.00	<		
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	143.00	<	168.00	<		
NA+	136-144 (MMOL/L)	01/05/91	140.00		141.00		141.00	
K+	3.6-5 (MMOL/L)	01/05/91	3.50	<	4.20		4.50	
CL-	95-105 (MMOL/L)	01/05/91	106.00	>	103.00		102.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.41		2.48		2.42	
PO4--	0.8-1.4 (MMOL/L)	01/05/91	1.44	>			1.40	
SGOT	5-25 (U/L)	01/05/91	11.00		9.00		9.00	
SGPT	5-35 (U/L)	01/05/91	12.00		17.00		15.00	
GAMMA GT	5-25 (U/L)	01/05/91	57.00	>>	27.00	>	16.00	
LDH	120-320 (U/L)	01/05/91	166.00		179.00		178.00	
ALK. PHOSPH.	35-85 (U/L)	01/05/91	47.00		62.00		58.00	
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	4.70		4.00		4.70	
UREA	2.8-7.4 (MMOL/L)	01/05/91	3.20		3.20		2.70 <	
CREATININE	55-100 (UMOL/L)	01/05/91	59.00		65.00		60.00	
URIC ACID	180-360 (UMOL/L)	01/05/91	277.00		288.00		273.00	
TOT. BILIRUBIN	3-20 (UMOL/L)	01/05/91	3.00		6.00		9.00	
TOT. PROTEINS	63-80 (G/L)	01/05/91	59.00	<	68.00		65.00	
ALBUMINE	38-50 (G/L)	01/05/91	39.40		47.40		45.40	
TOT. CHOLEST.	4-7 (MMOL/L)	01/05/91	5.12		5.47		5.24	
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	1.76	>	1.01		1.05	
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.60		2.40		2.10	
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	5.00		5.00		4.90	
GLOBULINS BETA	6-12 (G/L)	01/05/91	6.70		6.70		6.10	
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	5.30	<	6.60	<	6.60 <	
TSH	0.3-5 (UU/ML)	01/05/91	1.38					
T4	9.2-22.7 (PMOL/ML)	01/05/91	16.10					

1756

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/4 Patient: 179 Treatment: Placebo Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			08/09/92	30/09/92
			value (c)	value (c)
Laboratory test	Range value	Range date		
HB	11.5-17 (G/DL)	01/05/91	13.50	13.89
HT	36-52 (Z)	01/05/91	39.70	41.00
RBC	4.5-5.5 (10 ¹² /L)	01/05/91	4.51	4.65
MBC	4-10 (10 ⁹ /L)	01/05/91	6.70	7.70
MBC: N	2-7.5 (10 ⁹ /L)	01/05/91	4.22	4.93
MBC: L	1.5-4 (10 ⁹ /L)	01/05/91	1.94	2.31
MBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.20	0.08
MBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.27	0.31
MBC: B	0.04-0.5 (10 ⁹ /L)	01/05/91	0.07	0.08
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	231.00	264.00
NA+	136-144 (MMOL/L)	01/05/91	142.00	
K+	3.6-5 (MMOL/L)	01/05/91	4.40	
CL-	95-105 (MMOL/L)	01/05/91	102.00	
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.17	2.24
PO4--	0.8-1.4 (MMOL/L)	01/05/91	1.20	1.15
SGOT	5-25 (U/L)	01/05/91	4.00 <	9.00
SGPT	5-35 (U/L)	01/05/91	9.00	12.00
GAMMA GT	5-25 (U/L)	01/05/91	16.00	13.00
LDH	120-320 (U/L)	01/05/91	167.00	189.00
ALK. PHOSPH.	35-85 (U/L)	01/05/91	67.00	72.00
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	5.70	5.00
UREA	2.8-7.4 (MMOL/L)	01/05/91	8.30 >	6.00
CREATININE	55-100 (UMOL/L)	01/05/91	76.00	73.00
URIC ACID	180-360 (UMOL/L)	01/05/91	122.00 <	193.00
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	5.00	
TOT. PROTEINS	63-80 (G/L)	01/05/91	63.00	66.00
ALBUMINE	38-50 (G/L)	01/05/91	38.70	40.70
TOT. CHOLEST.	4-7 (MMOL/L)	01/05/91	6.09	5.67
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	0.78	0.78
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91	2.10	2.60
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91	4.50	4.90
GLOBULINS BETA	6-12 (G/L)	01/05/91	8.10	8.00
GLOBULINS GAMMA	7-15 (G/L)	01/05/91	9.60	9.90
TSH	0.3-5 (UU/ML)	01/05/91	1.29	
T4	9.2-22.7 (PMOL/ML)	01/05/91	11.60	

1757

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 4/4 Patient: 180 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/09/92		27/10/92		17/11/92	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	11.5-17 (G/DL)	01/05/91		14.70	14.50			
HT	36-52 (%)	01/05/91	44.40	41.40	43.20			
RBC	4-5.8 (10 ¹² /L)	01/05/91	4.62	4.41	4.61			
MBC	4-10 (10 ⁹ /L)	01/05/91	6.30	6.70	10.30 >			
MBC: N	2-7.5 (10 ⁹ /L)	01/05/91	3.53	4.09	8.03 >			
MBC: L	1.5-4 (10 ⁹ /L)	01/05/91	1.95	2.01	1.85			
MBC: E	0.04-0.5 (10 ⁹ /L)	01/05/91	0.32	0.27	0.21			
MBC: M	0.2-1 (10 ⁹ /L)	01/05/91	0.44	0.34	0.10 <			
MBC: B	0.01-0.1 (10 ⁹ /L)	01/05/91	0.06	0.00 <	0.10			
PLATELETS	200-400 (10 ⁹ /L)	01/05/91	208.00	197.00 <	209.00			
NA+	136-144 (MMOL/L)	01/05/91	138.00	139.00	141.00			
K+	3.6-5 (MMOL/L)	01/05/91	4.00	4.00	4.00			
CL-	95-105 (MMOL/L)	01/05/91	103.00	102.00	104.00			
Ca++	2.15-2.6 (MMOL/L)	01/05/91	2.37	2.32	2.35			
PO4--	0.8-1.4 (MMOL/L)	01/05/91		1.24	0.95			
SGOT	5-25 (U/L)	01/05/91	39.00 >	10.00	9.00			
SGPT	5-35 (U/L)	01/05/91	47.00 >	18.00	12.00			
GAMMA GT	5-25 (U/L)	01/05/91	67.00 >>	27.00 >	18.00			
LDH	120-320 (U/L)	01/05/91		154.00	191.00			
ALK. PHOSPH.	50-200 (U/L)	01/05/91	37.00 <	41.00 <	41.00 <			
GLUCOSE	3.9-5.8 (MMOL/L)	01/05/91	4.80	5.20	6.00 >			
BUN	()	01/05/91						
UREA	3.2-7.7 (MMOL/L)	01/05/91	4.20	3.80	4.00			
CREATININE	63-112 (UMOL/L)	01/05/91	81.00	76.00	76.00			
URIC ACID	240-420 (UMOL/L)	01/05/91	391.00	344.00	449.00 >			
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	14.00	7.00	4.00			
DIR BILIRUBIN	0-5 (UMOL/L)	01/05/91		2.00	2.00			
TOT. PROTEINS	63-80 (G/L)	01/05/91	60.00 <	61.00 <	65.00			
ALBUMINE	38-50 (G/L)	01/05/91		40.90	42.60			
TOT. CHOLEST.	3.5-5.2 (MMOL/L)	01/05/91	4.69	4.62	5.04			
TRIGLYCERIDES	0.5-1.6 (MMOL/L)	01/05/91	1.58	1.00	1.40			
GLOBULINS ALPHA 1	1-4 (G/L)	01/05/91		1.30	2.00			
GLOBULINS ALPHA 2	4-9 (G/L)	01/05/91		4.10	4.60			
GLOBULINS BETA	6-12 (G/L)	01/05/91		8.90	8.60			
GLOBULINS GAMMA	7-15 (G/L)	01/05/91		5.70 <	7.10			
TSH	0.3-5 (UU/ML)	01/05/91						
T4	9.2-22.7 (PMOL/ML)	01/05/91						

1758

(ϕ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 5/1 Patient: 127 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/06/91		27/06/91		18/07/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-17 (G/DL)	01/06/91	14.80		14.70		15.70	
HT	37-52 (X)	01/06/91	42.90		42.50		44.80	
RBC	4100000-5700000 (/UL)	01/06/91						
			4600000		4700000		4900000	
WBC	4000-10000 (/UL)	01/06/91	5370.00		6980.00		7620.00	
WBC: N	45-70 (%)	01/06/91	46.00		41.00 <		57.00	
WBC: L	20-40 (%)	01/06/91	51.00 >		40.00		39.00	
WBC: E	1-3 (%)	01/06/91	3.00		6.00 >>		4.00 >>	
WBC: M	3-7 (%)	01/06/91	0.00 <		3.00		0.00 <	
WBC: B	0-1 (%)	01/06/91	0.00		0.00		0.00	
PLATELETS	150000-400000 (/UL)	01/06/91						
			247000		253000		295000	
NA+	135-145 (MMOL/L)	01/06/91	141.00		139.00		140.00	
K+	3.5-5 (MMOL/L)	01/06/91	3.40 <		3.80		3.60	
CL-	95-110 (MMOL/L)	01/06/91	100.00		100.00		105.00	
Ca++	2.12-2.6 (MMOL/L)	01/06/91	2.41		2.43		2.44	
PO4--	0.81-1.62 (MMOL/L)	01/06/91	0.98		1.26		1.22	
SGOT	5-41 (UI/L)	01/06/91	37.00		18.00		21.00	
SGPT	5-41 (UI/L)	01/06/91	22.00		28.00		41.00	
GAMMA GT	11-50 (UI/L)	01/06/91	22.00		20.00		24.00	
LDH	220-440 (UI/L)	01/06/91	507.00 >				476.00 >	
ALK. PHOSPH.	100-290 (UI/L)	01/06/91	152.00		149.00		176.00	
GLUCOSE	3.9-5.8 (MMOL/L)	01/06/91	5.44		5.08		5.16	
UREA	1.7-8.3 (MMOL/L)	01/06/91	6.90		7.40		6.00	
CREATININE	62-110 (UMOL/L)	01/06/91	92.00		81.00		77.00	
URIC ACID	200-415 (UMOL/L)	01/06/91	343.00		602.00 >>		370.00	
TOT BILIRUBIN	3-17 (UMOL/L)	01/06/91	5.00		6.00		4.00	
TOT. PROTEINS	66-83 (G/L)	01/06/91	69.00		73.00		77.00	
ALBUMINE	57-70 (X)	01/06/91	56.50 <				42.27 <	
TOT. CHOLEST.	4-7 (MMOL/L)	01/06/91	5.05		5.13		5.84	
TRIGLYCERIDES	0.6-1.9 (MMOL/L)	01/06/91	1.22		1.52		1.30	
GLOBULINS ALPHA 1	2-4 (X)	01/06/91	2.30				2.30	
GLOBULINS ALPHA 2	10-14 (X)	01/06/91	9.80 <				9.20 <	
GLOBULINS BETA	6-13 (X)	01/06/91	11.80				14.80 >	
GLOBULINS GAMMA	10-19 (X)	01/06/91	19.60 >				18.80	
TSH	0.3-5 (UI/ML)	01/06/91	2.09					
T4	7-18 (PG/ML)	01/06/91	12.20					

1759

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/1 Patient: 128 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/06/91		05/07/91		26/07/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-17 (G/DL)	01/06/91	13.09		12.87		13.90	
HT	37-52 (X)	01/06/91	38.00		38.40		41.20	
RBC	4100000-5700000 (/UL)	01/06/91						
			4200000		4200000		4600000	
HBC	4000-10000 (/UL)	01/06/91	6860.00		5200.00		7320.00	
HBC: N	45-70 (X)	01/06/91	63.00		50.00		67.00	
HBC: L	20-40 (X)	01/06/91	33.00		40.00		29.00	
HBC: E	1-3 (X)	01/06/91	2.00		6.00	>>	3.00	
HBC: M	3-7 (X)	01/06/91	2.00	<	4.00		1.00	
HBC: B	0-1 (X)	01/06/91	0.00		0.00		0.00	
PLATELETS	150000-400000 (/UL)	01/06/91						
			214000		234000		271000	
NA+	135-145 (MMOL/L)	01/06/91	139.00		137.00		138.00	
K+	3.5-5 (MMOL/L)	01/06/91	3.90		3.60		3.70	
CL-	95-110 (MMOL/L)	01/06/91	101.00		98.00		104.00	
Ca++	2.12-2.6 (MMOL/L)	01/06/91	2.18		2.16		2.31	
PO4--	0.81-1.62 (MMOL/L)	01/06/91	1.07		1.30		1.11	
SGOT	5-36 (UI/L)	01/06/91	14.00		16.00		17.00	
SGPT	5-37 (UI/L)	01/06/91	12.00		12.00		14.00	
GAMMA GT	7-32 (UI/L)	01/06/91	15.00		14.00		25.00	
LDH	220-440 (UI/L)	01/06/91	421.00		457.00	>	512.00	
ALK. PHOSPH.	100-290 (UI/L)	01/06/91	131.00		130.00		144.00	
GLUCOSE	3.9-5.8 (MMOL/L)	01/06/91	4.33		4.43		4.95	
UREA	1.7-8.3 (MMOL/L)	01/06/91	4.10		4.00		4.00	
CREATININE	53-95 (UMOL/L)	01/06/91	66.00		65.00		66.00	
URIC ACID	140-340 (UMOL/L)	01/06/91	247.00		273.00		262.00	
TOT BILIRUBIN	3-17 (UMOL/L)	01/06/91	8.00		8.00		12.00	
TOT. PROTEINS	66-83 (G/L)	01/06/91	66.00		68.00		78.00	
ALBUMINE	57-70 (X)	01/06/91			58.70		59.50	
TOT. CHOLEST.	4-7 (MMOL/L)	01/06/91	5.13		5.35		5.78	
TRIGLYCERIDES	0.6-1.9 (MMOL/L)	01/06/91	0.89		0.74		0.78	
GLOBULINS ALPHA 1	2-4 (X)	01/06/91			2.50		1.80	
GLOBULINS ALPHA 2	10-14 (X)	01/06/91			10.00		11.30	
GLOBULINS BETA	6-13 (X)	01/06/91			12.10		10.90	
GLOBULINS GAMMA	10-19 (X)	01/06/91			16.70		16.50	
TSH	0.3-5 (UI/ML)	01/06/91	0.74					
T4	7-18 (PG/ML)	01/06/91	8.50					

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1760

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/1 Patient: 129 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/12/91		13/01/92		03/02/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-17 (G/DL)	20/12/91	15.00		16.66		16.00	
HT	37-52 (Z)	20/12/91	43.00		48.00		47.00	
RBC	4.1-5.7 (10 ⁶ /MM ³)	20/12/91	4.90		5.50		5.40	
HBC	4000-10000 (/UL)	20/12/91	4630.00		8600.00		8700.00	
HBC: N	45-70 (Z)	20/12/91	58.00		41.00	<	56.00	
HBC: L	20-40 (Z)	20/12/91	42.00	>	50.00	>>	44.00	
HBC: E	1-3 (Z)	20/12/91	0.00	<	6.00	>>	0.00	
HBC: M	3-7 (Z)	20/12/91	0.00	<	3.00	>	0.00	
HBC: B	0-1 (Z)	20/12/91	0.00		0.00		0.00	
PLATELETS	150000-400000 (/UL)	20/12/91	158000		283000		367000	
NA+	135-145 (MMOL/L)	20/12/91	137.00		140.00		140.00	
K+	3.5-5 (MMOL/L)	20/12/91	3.60		4.30		4.00	
CL-	95-110 (MMOL/L)	20/12/91	102.00		104.00		101.00	
Ca++	2.12-2.6 (MMOL/L)	20/12/91	2.44		2.57		2.55	
PO4--	0.81-1.62 (MMOL/L)	20/12/91	1.10		1.36		1.25	
SGOT	5-41 (UI/L)	20/12/91	28.00		22.00		21.00	
SGPT	5-41 (UI/L)	20/12/91	20.00		19.00		26.00	
GAMMA GT	11-50 (UI/L)	20/12/91	19.00		14.00		18.00	
LDH	220-440 (UI/L)	20/12/91	397.00		349.00		274.00	
ALK. PHOSPH.	100-290 (UI/L)	20/12/91	129.00		184.00		178.00	
GLUCOSE	0.7-1.05 (G/L)	20/12/91	0.93		0.81		0.77	
UREA	1.7-8.3 (MMOL/L)	20/12/91	3.50		3.80		3.30	
CREATININE	62-110 (UMOL/L)	20/12/91	92.00		89.00		75.00	
URIC ACID	200-415 (UMOL/L)	20/12/91	374.00		490.00	>	328.00	
TOT BILIRUBIN	3-17 (UMOL/L)	20/12/91	5.00		4.00		5.00	
DIR BILIRUBIN	0-7 (UMOL/L)	20/12/91	2.00		2.00		2.00	
TOT. PROTEINS	66-83 (G/L)	20/12/91	65.00	<	67.00		76.00	
ALBUMINE	37-42 (G/L)	20/12/91	37.00		41.67		47.00	
TOT. CHOLEST.	1.55-2.7 (G/L)	20/12/91	1.33	<				
	4-7 (MMOL/L)	12/01/92			4.18		3.48	
TRIGLYCERIDES	0.52-1.65 (G/L)	20/12/91	0.94					
	0.6-1.9 (MMOL/L)	12/01/92			0.72		0.70	
GLOBULINS ALPHA 1	1-3 (G/L)	20/12/91	2.67		1.94		1.75	
GLOBULINS ALPHA 2	4-7 (G/L)	20/12/91	8.26	>	10.40	>>	8.00	
GLOBULINS BETA	5-8 (G/L)	20/12/91	8.91	>	8.31	>	8.97	
GLOBULINS GAMMA	8-12 (G/L)	20/12/91	7.22	<	8.11		9.65	
TSH	0.3-5 (UI/ML)	20/12/91	3.52					
T4	7-18 (PG/ML)	20/12/91	8.58					

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1761

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/1 Patient: 130 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/02/92		25/03/92		15/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-17 (G/DL)	20/12/91	15.53		14.00		14.49	
HT	37-52 (X)	20/12/91	45.00		39.00		42.00	
RBC	4.1-5.7 (10 ⁶ /MM ³)	20/12/91	5.10		4.50		4.80	
WBC	4000-10000 (/UL)	20/12/91	8110.00		6500.00		6400.00	
WBC: N	45-70 (X)	20/12/91	59.00		49.00		52.00	
WBC: L	20-40 (X)	20/12/91	30.00		39.00		44.00 >	
WBC: E	1-3 (X)	20/12/91	6.00 >>		6.00 >>		1.00 >	
WBC: M	3-7 (X)	20/12/91	4.00		5.00		2.00 <	
WBC: B	0-1 (X)	20/12/91	1.00		1.00		1.00 <	
PLATELETS	150000-400000 (/UL)	20/12/91	359000		250000		273000	
NA+	135-145 (MMOL/L)	20/12/91	140.00		139.00		141.00	
K+	3.5-5 (MMOL/L)	20/12/91	3.90		3.90		4.20	
CL-	95-110 (MMOL/L)	20/12/91	105.00		102.00		103.00	
Ca++	2.12-2.6 (MMOL/L)	20/12/91	2.39		2.37		2.55	
PO4--	0.81-1.62 (MMOL/L)	20/12/91	1.27		1.33		0.90	
SGOT	5-41 (UI/L)	20/12/91	43.00 >		14.00		17.00	
SGPT	5-41 (UI/L)	20/12/91	35.00		13.00		11.00	
GAMMA GT	11-50 (UI/L)	20/12/91	40.00		15.00		13.00	
LDH	220-440 (UI/L)	20/03/92			187.00 <		228.00	
ALK. PHOSPH.	100-290 (UI/L)	20/12/91	171.00		134.00		140.00	
GLUCOSE	0.7-1.05 (G/L)	20/12/91	0.76		0.83		0.88	
UREA	0.1-0.5 (G/L)	20/12/91	0.28					
	1.7-8.3 (MMOL/L)	20/03/92			3.80		4.10	
CREATININE	62-110 (UMOL/L)	20/12/91	76.00		71.00		74.00	
URIC ACID	200-415 (UMOL/L)	20/12/91	296.00		323.00		380.00	
TOT. BILIRUBIN	3-17 (UMOL/L)	20/12/91	7.00		9.00		7.00	
DIR. BILIRUBIN	0-7 (UMOL/L)	20/12/91	0.90		4.00		1.00	
TOT. PROTEINS	66-83 (G/L)	20/12/91	66.00		64.00 <		73.00	
ALBUMINE	37-42 (G/L)	20/12/91	40.00		41.00		46.00 >	
TOT. CHOLEST.	1.55-2.7 (G/L)	20/12/91	1.80				1.55	
	4-7 (MMOL/L)	20/03/92			4.00			
TRIGLYCERIDES	0.52-1.65 (G/L)	20/12/91	0.71				0.39 <	
	0.6-1.9 (MMOL/L)	20/03/92			0.46 <			
GLOBULINS ALPHA 1	1-3 (G/L)	20/12/91	2.50		1.15		1.46	
GLOBULINS ALPHA 2	4-7 (G/L)	20/12/91	5.60		4.99		6.35	
GLOBULINS BETA	5-8 (G/L)	20/12/91	7.70		7.10		8.03 >	
GLOBULINS GAMMA	8-12 (G/L)	20/12/91	9.60		9.40		10.73	
TSH	0.3-5 (UI/ML)	20/12/91	0.30					
T4	7-18 (PG/ML)	20/12/91	15.60					

1762

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/1 Patient: 131 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/03/92		10/04/92		30/04/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-17 (G/DL)	15/03/92	12.00		14.31		13.88	
HT	37-52 (X)	15/03/92	35.55	<	41.00		41.00	
RBC	4.1-5.7 (10 ⁶ /MM ³)	15/03/92	4.06	<	4.70		4.70	
HBC	4000-10000 (/UL)	15/03/92	4360.00		6070.00		6400.00	
HBC: N	45-70 (X)	15/03/92	59.00		67.00		60.00	
HBC: L	20-40 (X)	15/03/92	41.00	>	32.00		38.00	
HBC: E	1-3 (X)	15/03/92	0.00	<	0.00	<	0.00	<
HBC: M	3-7 (X)	15/03/92	0.00	<	1.00	<	2.00	<
HBC: B	0-1 (X)	15/03/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/UL)	15/03/92	193000		266000		307000	
NA+	135-145 (MMOL/L)	15/03/92	141.00		138.00		140.00	
K+	3.5-5 (MMOL/L)	15/03/92	3.90		4.00		3.60	
CL-	95-110 (MMOL/L)	15/03/92	107.00		101.00		102.00	
Ca++	2.12-2.6 (MMOL/L)	15/03/92	2.22		2.47		2.56	
PO4--	0.81-1.62 (MMOL/L)	15/03/92	1.17	<	0.77	<	0.85	
SGOT	5-36 (UI/L)	15/03/92	34.00		14.00		18.00	
SGPT	5-37 (UI/L)	15/03/92	40.00	>	15.00		20.00	
GAMMA GT	7-32 (UI/L)	15/03/92	34.00	>	5.00	<	28.00	
LDH	220-440 (UI/L)	15/03/92	270.00		226.00		288.00	
ALK. PHOSPH.	100-290 (UI/L)	15/03/92	144.00		170.00		154.00	
GLUCOSE	0.7-1.05 (G/L)	15/03/92	0.87		0.95		1.06	>
UREA	1.7-8.3 (MMOL/L)	15/03/92	5.90		3.60		3.80	
CREATININE	53-95 (UMOL/L)	15/03/92	67.00		76.00		77.00	
URIC ACID	140-340 (UMOL/L)	15/03/92	259.00		261.00			
TOT BILIRUBIN	3-17 (UMOL/L)	15/03/92	3.00		5.00		4.00	
DIR BILIRUBIN	0-7 (UMOL/L)	15/03/92	0.20		2.00			
TOT. PROTEINS	66-83 (G/L)	15/03/92	62.00	<	70.00		70.00	
ALBUMINE	37-42 (G/L)	15/03/92	35.00	<	43.60	>	41.09	
TOT. CHOLEST.	1.55-2.7 (G/L)	15/03/92	2.42		2.43		2.22	
TRIGLYCERIDES	0.52-1.65 (G/L)	15/03/92	3.33	>>	1.11		1.15	
GLOBULINS ALPHA 1	1-3 (G/L)	15/03/92	1.43		1.68		2.03	
GLOBULINS ALPHA 2	4-7 (G/L)	15/03/92	8.99	>	7.63	>	8.68	>
GLOBULINS BETA	5-8 (G/L)	15/03/92	8.80	>	8.40	>	9.38	>
GLOBULINS GAMMA	8-12 (G/L)	15/03/92	7.75	<	8.68		8.82	

1763

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 5/1 Patient: 132 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/06/92		16/07/92		10/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-17 (G/DL)	20/06/92	16.00		15.01		14.25	
HT	37-52 (%)	20/06/92	46.40		45.04		42.23	
RBC	4.1-5.7 (10 ⁶ /MM ³)	20/06/92	5.07		5.00		4.75	
WBC	4000-10000 (/UL)	20/06/92	7040.00		7650.00		8420.00	
WBC: N	45-70 (%)	20/06/92	49.00		34.00 <		54.00	
WBC: L	20-40 (%)	20/06/92	51.00 >		60.00 >>		44.00 >	
WBC: E	1-3 (%)	20/06/92	0.00 <		4.00 >>		2.00	
WBC: M	3-7 (%)	20/06/92	0.00 <		0.00 <		0.00 <	
WBC: B	0-1 (%)	20/06/92	0.00		2.00 >>		0.00	
PLATELETS	150000-400000 (/UL)	20/06/92	258000		270000		312000	
NA+	135-145 (MMOL/L)	20/06/92	141.00		135.00		137.00	
K+	3.5-5 (MMOL/L)	20/06/92	4.00		3.80		3.90	
CL-	95-110 (MMOL/L)	20/06/92	106.00		103.00		103.00	
Ca++	2.12-2.6 (MMOL/L)	20/06/92	2.48		2.65 >		2.39	
PO4--	0.81-1.62 (MMOL/L)	20/06/92	1.31		1.53		1.30	
SGOT	5-41 (UI/L)	20/06/92	18.00				22.00	
SGPT	5-41 (UI/L)	20/06/92	38.00				51.00 >	
GAMMA GT	11-50 (UI/L)	20/06/92	45.00		50.00		36.00	
LDH	220-440 (UI/L)	20/06/92	263.00		276.00		328.00	
ALK. PHOSPH.	100-290 (UI/L)	20/06/92	138.00		123.00		137.00	
GLUCOSE	3.9-5.8 (MMOL/L)	20/06/92	5.66		5.60		4.99	
UREA	1.7-8.3 (MMOL/L)	20/06/92	4.00		4.40		3.40	
CREATININE	62-110 (UMOL/L)	20/06/92	80.00		91.00		86.00	
URIC ACID	200-415 (UMOL/L)	20/06/92	350.00		419.00 >		353.00	
TOT BILIRUBIN	3-17 (UMOL/L)	20/06/92	10.00		6.00		5.00	
DIR BILIRUBIN	0-7 (UMOL/L)	20/06/92	1.30					
TOT. PROTEINS	66-83 (G/L)	20/06/92	59.00 <		74.00		70.00	
ALBUMINE	37-42 (G/L)	20/06/92	52.90 >		46.40 >		44.17 >	
TOT. CHOLEST.	4-7 (MMOL/L)	20/06/92	7.05 >		7.66 >		5.32	
TRIGLYCERIDES	0.6-1.9 (MMOL/L)	20/06/92	1.76		1.35		1.28	
GLOBULINS ALPHA 1	1-3 (G/L)	20/06/92	1.53		1.55		1.96	
GLOBULINS ALPHA 2	4-7 (G/L)	20/06/92	6.25		6.51		7.42 >	
GLOBULINS BETA	5-8 (G/L)	20/06/92	6.84		8.88 >		7.84	
GLOBULINS GAMMA	8-12 (G/L)	20/06/92	9.50		10.58		8.61	
TSH	0.3-5 (UI/ML)	20/06/92	0.88					
T4	7-18 (PG/ML)	20/06/92	11.29					

1764

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 5/2 Patient: 121 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/12/91		10/01/92		28/01/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	24/01/91	13.40		15.00		13.20	
HT	37-48 (%)	24/01/91	40.10		44.00		39.30	
RBC	3.9-5.3 (10 ⁶ /UL)	24/01/91	4.30		4.80		4.25	
WBC	4-10 (10 ³ /UL)	24/01/91	6.10		5.60		6.50	
WBC: N	40-75 (%)	24/01/91	59.00		63.00		56.00	
WBC: L	20-45 (%)	24/01/91	40.00		32.00		40.00	
WBC: E	1-5 (%)	24/01/91	1.00		3.00		1.00	
WBC: M	2-10 (%)	24/01/91	0.00	<	2.00		3.00	
WBC: B	0-4 (%)	24/01/91	0.00		0.00		0.00	
PLATELETS	250-450 (10 ³ /UL)	24/01/91	228.00	<	190.00	<	245.00	
NA+	138-145 (MMOL/L)	24/01/91	142.00		140.00		143.00	
K+	3.5-5 (MMOL/L)	24/01/91	4.20		4.50		3.90	
CL-	98-106 (MMOL/L)	24/01/91	101.00		102.00		106.00	
Ca++	2.2-2.55 (MMOL/L)	24/01/91	2.32		2.48		2.08	
PO4--	0.9-1.5 (MMOL/L)	24/01/91	1.43		1.30		1.42	
SGOT	5-40 (UI/L)	24/01/91	6.00		8.00		8.00	
SGPT	5-40 (UI/L)	24/01/91	4.00	<	4.00	<	5.00	
GAMMA GT	5-40 (UI/L)	24/01/91	10.00		11.00		8.00	
LDH	120-300 (UI/ML)	24/01/91	244.00		280.00		238.00	
ALK. PHOSPH.	50-90 (UI/L)	24/01/91	28.00	<	28.00	<	24.00	
GLUCOSE	4-6 (MMOL/L)	24/01/91	4.20		4.35		4.00	
CREATININE	50-110 (UMOL/L)	24/01/91	77.00		98.00		59.00	
URIC ACID	150-360 (UMOL/L)	24/01/91	4.50	<	9.50	<	4.50	
TOT. BILIRUBIN	1.7-17 (UMOL/L)	24/01/91	17.00		17.00		17.00	
TOT. PROTEINS	64-80 (G/L)	24/01/91	68.00		76.00		61.00	
ALBUMINE	27-44 (G/L)	24/01/91	56.00	>	52.20	>		
TOT. CHOLEST.	3.5-7 (MMOL/L)	24/01/91	5.45		6.90		4.80	
TRIGLYCERIDES	0.4-1.9 (MMOL/L)	24/01/91	1.46		1.45		1.10	
GLOBULINS ALPHA 1	1-4 (G/L)	24/01/91	4.65	>	2.70	>>	2.10	
GLOBULINS ALPHA 2	5-10 (G/L)	24/01/91	11.50	>	13.30	>>	8.30	
GLOBULINS BETA	6-12 (G/L)	24/01/91	13.40	>	14.10	>	8.30	
GLOBULINS GAMMA	6-16 (G/L)	24/01/91	14.50	>	17.70	>	9.50	
TSH	0.2-4 (UI/ML)	24/01/91	1.60					
T4	5-13 (NG/100ML)	24/01/91	8.50					

1765

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/2 Patient: 125 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/01/91		11/02/91		11/03/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	24/01/91	14.70		15.90		15.40	
HT	40-54 (X)	24/01/91	44.90		47.70		44.80	
RBC	4.3-5.7 (10 ⁶ /UL)	24/01/91	4.84		5.15		5.03	
HBC	4-10 (10 ³ /UL)	24/01/91	9.90		6.30		6.40	
HBC: N	40-75 (X)	24/01/91	56.00		48.00		40.00	
HBC: L	20-45 (X)	24/01/91	39.00		47.00	>	54.00 >	
HBC: E	1-5 (X)	24/01/91	2.00		1.00		2.00	
HBC: H	2-10 (X)	24/01/91	3.00		4.00		4.00	
HBC: B	0-4 (X)	24/01/91	0.00		0.00		0.00	
PLATELETS	250-450 (10 ³ /UL)	24/01/91	321.00		290.00		400.00	
NA+	138-145 (MMOL/L)	24/01/91	143.00		143.00		142.00	
K+	3.5-5 (MMOL/L)	24/01/91	3.70		4.10		4.50	
CL-	98-106 (MMOL/L)	24/01/91	104.00		104.00		107.00 >	
Ca++	2.2-2.55 (MMOL/L)	24/01/91	2.35		2.35		2.40	
PO4--	0.8-1.44 (MMOL/L)	24/01/91	1.25		1.15		1.16	
SGOT	5-40 (UI/L)	24/01/91	16.00		19.00		19.00	
SGPT	5-40 (UI/L)	24/01/91	44.00	>	45.00	>	28.00	
GAMMA GT	5-40 (UI/L)	24/01/91	54.00	>	44.00	>	35.00	
LDH	120-300 (UI/ML)	24/01/91	201.00		214.00		260.00	
ALK. PHOSPH.	50-90 (UI/L)	24/01/91	42.00	<	41.00	<	49.00 <	
GLUCOSE	4-6 (MMOL/L)	24/01/91	4.20		5.00		5.30	
UREA	2.5-7.5 (MMOL/L)	24/01/91	7.10		4.80		5.30	
CREATININE	50-110 (UMOL/L)	24/01/91	88.00		32.00	<	95.00	
URIC ACID	150-420 (UMOL/L)	24/01/91	339.00		320.00		299.00	
TOT BILIRUBIN	1.7-17 (UMOL/L)	24/01/91	17.00		17.00		17.00	
TOT. PROTEINS	64-80 (G/L)	24/01/91	71.00		71.00		76.00	
ALBUMINE	27-44 (G/L)	24/01/91	48.00	>	35.70		39.50	
TOT. CHOLEST.	3.5-7 (MMOL/L)	24/01/91	4.20		5.10			
TRIGLYCERIDES	0.4-1.9 (MMOL/L)	24/01/91	1.50		2.00	>		
GLOBULINS ALPHA 1	1-4 (G/L)	24/01/91	1.40		1.70		1.70	
GLOBULINS ALPHA 2	5-10 (G/L)	24/01/91	6.90		7.00		8.80	
GLOBULINS BETA	6-12 (G/L)	24/01/91	8.70		10.00		10.40	
GLOBULINS GAMMA	6-16 (G/L)	24/01/91	15.80		15.70		17.20 >	
TSH	0.2-4 (UI/ML)	24/01/91	1.20					
T4	5-13 (NG/100ML)	24/01/91	5.00					

1766

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/3 Patient: 133 Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Screen		Day 14	
			26/11/91		13/12/91	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	12-18 (G/DL)	01/10/91	15.90		15.40	
HT	35-55 (%)	01/10/91	48.60		46.40	
RBC	3.5-6 (10 ⁶ /UL)	01/10/91	5.26		4.97	
MBC	3.5-11 (10 ³ /UL)	01/10/91	6.92		8.45	
MBC: N	50-70 (%)	01/10/91	56.10		56.00	
MBC: L	25-45 (%)	01/10/91	28.80		30.80	
MBC: E	1-5 (%)	01/10/91	4.00		3.60	
MBC: M	2-10 (%)	01/10/91	10.10	>	8.50	
MBC: B	0.25-0.75 (%)	01/10/91	0.50		0.80 >	
PLATELETS	125-425 (10 ³ /UL)	01/10/91	281.00		267.00	
NA+	138-145 (MMOL/L)	01/10/91	141.00		141.00	
K+	3.8-5 (MMOL/L)	01/10/91	4.50		5.00	
CL-	98-107 (MMOL/L)	01/10/91	102.00		102.00	
Ca++	2.3-2.55 (MMOL/L)	01/10/91	2.39		2.61 >	
PO4--	0.9-1.75 (MMOL/L)	01/10/91	1.29		1.34	
SGOT	5-25 (UI/L)	01/10/91	15.00		13.00	
SGPT	5-32 (UI/L)	01/10/91	16.00		14.00	
GAMMA GT	5-37 (UI/L)	01/10/91	18.00		18.00	
LDH	120-300 (UI/L)	01/10/91	195.00		181.00	
ALK. PHOSPH.	30-100 (UI/L)	01/10/91	91.00		89.00	
GLUCOSE	4.2-6.2 (MMOL/L)	01/10/91	5.20		5.00	
UREA	3.5-7.5 (MMOL/L)	01/10/91	6.10		6.30	
CREATININE	80-115 (UMOL/L)	01/10/91	114.00		113.00	
URIC ACID	150-420 (UMOL/L)	01/10/91	384.00		551.00 >>	
TOT BILIRUBIN	7-17 (UMOL/L)	01/10/91	21.00	>	15.00	
TOT. PROTEINS	65-77 (G/L)	01/10/91	71.00		73.00	
ALBUMINE	35-50 (G/L)	01/10/91	38.90		39.50	
TOT. CHOLEST.	3.7-5.8 (MMOL/L)	01/10/91	6.80	>	6.10 >	
TRIGLYCERIDES	0.69-1.61 (MMOL/L)	01/10/91	1.11		1.37	
GLOBULINS ALPHA 1	2.5-5.7 (G/L)	01/10/91	1.90	<	2.30 <	
GLOBULINS ALPHA 2	4.1-10.1 (G/L)	01/10/91	6.50		6.80	
GLOBULINS BETA	5.6-12.6 (G/L)	01/10/91	11.80		13.30 >	
GLOBULINS GAMMA	7.8-19.3 (G/L)	01/10/91	11.50		11.10	
TSH	0.2-4 (MUI/L)	01/10/91	1.01			
T4	13-29 (PMOL/L)	01/10/91	12.80	<		

1767

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/3 Patient: 134 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/12/91		27/12/91		16/01/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/10/91	13.00		13.80		13.30	
HT	35-55 (%)	01/10/91	39.50		40.90		39.60	
RBC	3.5-6 (10 ⁶ /UL)	01/10/91	4.13		4.34		4.14	
WBC	3.5-11 (10 ³ /UL)	01/10/91	3.91		4.58		4.31	
WBC: N	50-70 (%)	01/10/91	49.90 <		57.40		48.50 <	
WBC: L	25-45 (%)	01/10/91	38.00		27.40		37.30	
WBC: E	1-5 (%)	01/10/91	4.20		4.50		5.90 >	
WBC: M	8-10 (%)	01/10/91	6.70 <		9.60		6.70 <	
WBC: B	0.25-0.75 (%)	01/10/91	0.50		0.50		0.90 >	
PLATELETS	125-425 (10 ³ /UL)	01/10/91	250.00		334.00		341.00	
NA+	138-145 (MMOL/L)	01/10/91	136.00 <		138.00		138.00	
K+	3.8-5 (MMOL/L)	01/10/91	4.20		4.00		4.60	
CL-	98-107 (MMOL/L)	01/10/91	98.00		98.00		101.00	
Ca++	2.3-2.55 (MMOL/L)	01/10/91	2.42		2.36		2.34	
PO4--	0.9-1.75 (MMOL/L)	01/10/91	1.62		1.33		1.10	
SGOT	5-25 (UI/L)	01/10/91	16.00		17.00		19.00	
SGPT	5-32 (UI/L)	01/10/91	21.00		23.00		22.00	
GAMMA GT	5-37 (UI/L)	01/10/91	60.00 >		61.00 >		50.00 >	
LDH	120-300 (UI/L)	01/10/91	174.00		212.00		194.00	
ALK. PHOSPH.	30-100 (UI/L)	01/10/91	24.00 <		25.00 <		32.00	
GLUCOSE	4.2-6.2 (MMOL/L)	01/10/91	4.80		5.40		5.00	
UREA	3.5-7.5 (MMOL/L)	01/10/91	4.50		5.00		4.20	
CREATININE	80-115 (UMOL/L)	01/10/91	88.00		71.00 <		77.00 <	
URIC ACID	150-420 (UMOL/L)	01/10/91	244.00		246.00		171.00	
TOT. BILIRUBIN	7-17 (UMOL/L)	01/10/91	13.00		13.00		11.00	
TOT. PROTEINS	65-77 (G/L)	01/10/91	68.00		71.00		80.00 >	
ALBUMINE	35-50 (G/L)	01/10/91	42.70		40.50		43.20	
TOT. CHOLEST.	3.7-5.8 (MMOL/L)	01/10/91	4.70		5.50		5.40	
TRIGLYCERIDES	0.69-1.61 (MMOL/L)	01/10/91	0.81		0.55 <		1.12	
GLOBULINS ALPHA 1	2.5-5.7 (G/L)	01/10/91			2.30 <		3.00	
GLOBULINS ALPHA 2	4.1-10.1 (G/L)	01/10/91			5.80		8.20	
GLOBULINS BETA	5.6-12.6 (G/L)	01/10/91			10.10		11.40	
GLOBULINS GAMMA	7.8-19.3 (G/L)	01/10/91			12.30		14.20	
TSH	0.2-4 (MUI/L)	01/10/91	0.38					
T4	13-29 (PMOL/L)	01/10/91	17.60					

1768

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/3 Patient: 135 Treatment: Imipramine Sex: Female

Laboratory test			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/01/92		30/01/92		20/02/92	
			value	(c)	value	(c)	value	(c)
Range value	Range date							
HB	12-18 (G/DL)	01/10/91	13.40		12.80		13.00	
HT	35-55 (%)	01/10/91	39.50		38.50		40.50	
RBC	3.5-6 (10 ⁶ /UL)	01/10/91	4.36		4.21		4.53	
WBC	3.5-11 (10 ³ /UL)	01/10/91	5.90		6.58		6.02	
WBC: N	50-70 (%)	01/10/91	52.70		61.60		61.80	
WBC: L	25-45 (%)	01/10/91	34.70		29.20		28.40	
WBC: E	1-5 (%)	01/10/91	3.00		2.20		1.30	
WBC: M	8-10 (%)	01/10/91	7.80	<	6.70	<	6.60	
WBC: B	0.25-0.75 (%)	01/10/91	0.70		0.00	<	1.40	
PLATELETS	125-425 (10 ³ /UL)	01/10/91	316.00		304.00		372.00	
NA+	138-145 (MMOL/L)	01/10/91	139.00		138.00		138.00	
K+	3.8-5 (MMOL/L)	01/10/91	4.70		4.50		4.40	
CL-	98-107 (MMOL/L)	01/10/91	103.00		100.00		105.00	
Ca++	2.3-2.55 (MMOL/L)	01/10/91	2.48		2.27	<	2.31	
PO4--	0.9-1.75 (MMOL/L)	01/10/91			1.15		1.13	
SGOT	5-25 (UI/L)	01/10/91	16.00		14.00		17.00	
SGPT	5-32 (UI/L)	01/10/91	20.00		18.00		24.00	
GAMMA GT	5-37 (UI/L)	01/10/91	22.00		21.00		25.00	
LDH	120-300 (UI/L)	01/10/91			190.00		249.00	
ALK. PHOSPH.	30-100 (UI/L)	01/10/91					56.00	
GLUCOSE	4.2-6.2 (MMOL/L)	01/10/91	5.10		4.60		3.80	
UREA	3.5-7.5 (MMOL/L)	01/10/91	6.50		4.00		5.00	
CREATININE	80-115 (UMOL/L)	01/10/91	90.00		88.00		112.00	
URIC ACID	150-420 (UMOL/L)	01/10/91			235.00		225.00	
TOT. BILIRUBIN	7-17 (UMOL/L)	01/10/91	8.00		10.00		10.00	
TOT. PROTEINS	65-77 (G/L)	01/10/91	73.00		67.00		74.00	
ALBUMINE	35-50 (G/L)	01/10/91	40.40		33.70	<	41.40	
TOT. CHOLEST.	3.7-5.8 (MMOL/L)	01/10/91	6.70	>	5.30		6.20	
TRIGLYCERIDES	0.69-1.61 (MMOL/L)	01/10/91	0.91		0.78			
GLOBULINS ALPHA 1	2.5-5.7 (G/L)	01/10/91	2.30	<	1.90	<	2.60	
GLOBULINS ALPHA 2	4.1-10.1 (G/L)	01/10/91	8.20		8.50		7.70	
GLOBULINS BETA	5.6-12.6 (G/L)	01/10/91	11.70		13.10	>	12.10	
GLOBULINS GAMMA	7.8-19.3 (G/L)	01/10/91	10.40		9.80		10.20	
TSH	0.2-4 (MUI/L)	01/10/91	2.26					
T4	13-29 (PMOL/L)	01/10/91	13.10					

1769

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/3 Patient: 136 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/03/92		24/03/92		13/04/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/10/91	14.40		14.80		15.20	
HT	35-55 (%)	01/10/91	44.00		44.00		44.40	
RBC	3.5-6 (10 ⁶ /UL)	01/10/91	4.88		4.85		5.00	
HBC	3.5-11 (10 ³ /UL)	01/10/91	6.20		7.19		8.80	
MBC: N	50-70 (%)	01/10/91	36.70	<	49.10	<	46.90	
MBC: L	25-45 (%)	01/10/91	53.10	>	41.50		43.20	
MBC: E	1-5 (%)	01/10/91	4.40		2.60		3.20	
MBC: M	8-10 (%)	01/10/91	4.70	<	5.90	<	5.40	
MBC: B	0.25-0.75 (%)	01/10/91	0.90	>	0.20	<	0.20	
PLATELETS	125-425 (10 ³ /UL)	01/10/91	314.00		259.00		289.00	
NA+	138-145 (MMOL/L)	01/10/91	138.00		136.00	<	137.00	
K+	3.8-5 (MMOL/L)	01/10/91	4.10		4.20		4.50	
CL-	98-107 (MMOL/L)	01/10/91	102.00		96.00	<	102.00	
Ca++	2.3-2.55 (MMOL/L)	01/10/91	2.32		2.41		2.49	
PO4--	0.9-1.75 (MMOL/L)	01/10/91	1.13		1.33		1.25	
SGOT	5-25 (UI/L)	01/10/91	22.00		36.00	>	30.00	
SGPT	5-32 (UI/L)	01/10/91	46.00	>	80.00	>>	59.00	
GAMMA GT	5-37 (UI/L)	01/10/91	246.00	>>	194.00	>>	260.00	
LDH	120-300 (UI/L)	01/10/91	255.00		291.00		292.00	
ALK. PHOSPH.	30-100 (UI/L)	01/10/91	84.00		84.00		93.00	
GLUCOSE	4.2-6.2 (MMOL/L)	01/10/91	5.60		5.10		6.10	
UREA	3.5-7.5 (MMOL/L)	01/10/91	6.30		6.40		5.50	
CREATININE	80-115 (UMOL/L)	01/10/91	98.00		86.00		109.00	
URIC ACID	150-420 (UMOL/L)	01/10/91	339.00		384.00		314.00	
TOT. BILIRUBIN	7-17 (UMOL/L)	01/10/91	12.00		12.00		13.00	
TOT. PROTEINS	65-77 (G/L)	01/10/91	74.00		76.00		82.00	
ALBUMINE	35-50 (G/L)	01/10/91	41.80		41.70		45.60	
TOT. CHOLEST.	3.7-5.8 (MMOL/L)	01/10/91	6.60	>	7.10	>	6.70	
TRIGLYCERIDES	0.69-1.61 (MMOL/L)	01/10/91	3.56	>>	1.66	>		
GLOBULINS ALPHA 1	2.5-5.7 (G/L)	01/10/91	2.30	<	2.70		2.10	
GLOBULINS ALPHA 2	4.1-10.1 (G/L)	01/10/91	7.10		7.40		8.30	
GLOBULINS BETA	5.6-12.6 (G/L)	01/10/91	11.40		11.80		12.30	
GLOBULINS GAMMA	7.8-19.3 (G/L)	01/10/91	11.40		12.40		13.70	
TSH	0.2-4 (MUI/L)	01/10/91	0.48					
T4	13-29 (PMOL/L)	01/10/91	14.40					

1770

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 5/3 Patient: 137 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			12/05/92		05/06/92		25/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/05/92	14.60		14.30		12.30	
HT	35-55 (%)	01/05/92	43.80		43.90		36.90	
RBC	3.5-6 (10 ⁶ /UL)	01/05/92	4.89		4.86		4.02	
RBC	3.5-11 (10 ³ /UL)	01/05/92	7.65		10.58		5.81	
HBC: N	2-8.6 (10 ³ /UL)	01/05/92	3.73		7.40		3.29	
HBC: L	0.8-4 (10 ³ /UL)	01/05/92	3.12		2.24		2.02	
HBC: E	0.04-0.5 (10 ³ /UL)	01/05/92	0.14		0.09		0.09	
HBC: M	0.1-1 (10 ³ /UL)	01/05/92	0.63		0.77		0.34	
HBC: B	0.01-0.1 (10 ³ /UL)	01/05/92	0.00	<	0.00	<	0.02	
PLATELETS	125-425 (10 ³ /UL)	01/05/92	229.00		204.00		228.00	
NA+	138-145 (MMOL/L)	01/05/92	135.00	<	139.00		138.00	
K+	3.8-5 (MMOL/L)	01/05/92	3.80		4.20		4.20	
CL-	98-107 (MMOL/L)	01/05/92	98.00		105.00		102.00	
Ca++	2.3-2.55 (MMOL/L)	01/05/92	2.44		2.47		2.20 <	
PO4--	0.9-1.75 (MMOL/L)	01/05/92	0.97		1.23		1.11	
SGOT	5-25 (UI/L)	01/05/92	15.00		14.00		14.00	
SGPT	5-32 (UI/L)	01/05/92	9.00		11.00		11.00	
GAMMA GT	5-37 (UI/L)	01/05/92	12.00		11.00		11.00	
LDH	120-300 (UI/L)	01/05/92	188.00		196.00		191.00	
ALK. PHOSPH.	30-100 (UI/L)	01/05/92	29.00	<	32.00		30.00	
GLUCOSE	4.2-6.2 (MMOL/L)	01/05/92	4.40		4.90		5.10	
UREA	3.5-7.5 (MMOL/L)	01/05/92	2.00	<	4.40		4.60	
CREATININE	80-115 (UMOL/L)	01/05/92	66.00	<	65.00	<	75.00 <	
URIC ACID	150-420 (UMOL/L)	01/05/92	319.00	<	135.00	<	213.00	
TOT. BILIRUBIN	7-17 (UMOL/L)	01/05/92	15.00		11.00		8.00	
TOT. PROTEINS	65-77 (G/L)	01/05/92	79.00	>	84.00	>	75.00	
ALBUMINE	54-65 (%)	01/05/92	46.90	>	42.00	<	44.10 <	
TOT. CHOLEST.	3.7-5.8 (MMOL/L)	01/05/92	6.00	>	4.50		3.60 <	
TRIGLYCERIDES	0.69-1.61 (MMOL/L)	01/05/92	1.66	>	1.42		0.69	
GLOBULINS ALPHA 1	2-5 (%)	01/05/92	2.70		2.80		2.60	
GLOBULINS ALPHA 2	6-10 (%)	01/05/92	9.20		8.20		5.90 <	
GLOBULINS BETA	10-16 (%)	01/05/92	13.10		12.60		10.50	
GLOBULINS GAMMA	11-21 (%)	01/05/92	15.60		18.40		11.90	
TSH	0.2-4 (MUI/L)	01/05/92	0.93					
T4	13-29 (PMOL/L)	01/05/92	21.70					

1771

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 5/3 Patient: 138 Treatment: Placebo Sex: Female

			Visit number / Laboratory date			
			Screen		Follow up	
			14/05/92		04/06/92	
			value	(ø)	value	(ø)
Laboratory test	Range value	Range date				
HB	12-18 (G/DL)	01/05/92	13.40			
	12-16 (G/DL)	01/06/92			13.70	
HT	35-55 (X)	01/05/92	41.40			
	36-53 (X)	01/06/92			41.40	
RBC	3.5-6 (10 ⁶ /UL)	01/05/92	4.45			
	4-5 (10 ⁶ /MM3)	01/06/92			4.49	
WBC	3.5-11 (10 ³ /UL)	01/05/92	6.06			
	4-10 (10 ³ /MM3)	01/06/92			7.70	
WBC: N	60-70 (%)	01/05/92	67.80			
WBC: L	20-30 (%)	01/05/92	22.60			
WBC: E	1-3 (%)	01/05/92	6.30	>>	4.00	>>
WBC: M	5-10 (%)	01/05/92	3.10	<	4.00	<
WBC: B	0-1 (%)	01/05/92	0.10		0.00	
PLATELETS	125-425 (10 ³ /UL)	01/05/92	98.00	<		
	()	01/06/92				
NA+	()	01/06/92				
	138-145 (MMOL/L)	01/05/92	140.00			
K+	()	01/06/92				
	3.8-5 (MMOL/L)	01/05/92	3.90			
CL-	()	01/06/92				
	98-107 (MMOL/L)	01/05/92	95.00	<		
Ca++	()	01/06/92				
	2.3-2.55 (MMOL/L)	01/05/92	2.26	<		
PO4--	()	01/06/92				
	0.9-1.75 (MMOL/L)	01/05/92	1.28			
SGOT	5-25 (UI/L)	01/05/92	720.00	>>		
	10-35 (UI/L)	01/06/92			18.00	
SGPT	5-32 (UI/L)	01/05/92	575.00	>>		
	10-44 (UI/L)	01/06/92			49.00	>
GAMMA GT	5-37 (UI/L)	01/05/92	127.00	>>		
	7-32 (UI/L)	01/06/92			60.00	>
LDH	120-300 (UI/L)	01/05/92	924.00	>>		
	150-450 (UI/L)	01/06/92			154.00	
ALK. PHOSPH.	30-100 (UI/L)	01/05/92	36.00			
	39-117 (UI/L)	01/06/92			41.00	
GLUCOSE	()	01/06/92				
	4.2-6.2 (MMOL/L)	01/05/92	4.90			
BUN	()	01/05/92				
UREA	()	01/06/92				
	3.5-7.5 (MMOL/L)	01/05/92	3.50			
CREATININE	()	01/06/92				
	80-115 (UMOL/L)	01/05/92	69.00	<		
URIC ACID	()	01/06/92				
	150-420 (UMOL/L)	01/05/92	253.00			
TOT BILIRUBIN	7-17 (UMOL/L)	01/05/92	9.00			
	2-12 (MG/L)	01/06/92			5.00	
DIR BILIRUBIN	()	01/05/92				
TOT. PROTEINS	()	01/06/92				
	65-77 (G/L)	01/05/92	67.00			
ALBUMINE	35-50 (G/L)	01/05/92	36.30			
	37-48 (G/L)	01/06/92				
TOT. CHOLEST.	()	01/06/92				
	3.7-5.8 (MMOL/L)	01/05/92	5.40			
TRIGLYCERIDES	()	01/06/92				
	0.69-1.61 (MMOL/L)	01/05/92	0.94			
GLOBULINS ALPHA 1	2.5-5.7 (G/L)	01/05/92	2.60			
	2-3 (G/L)	01/06/92				
GLOBULINS ALPHA 2	4.1-10.1 (G/L)	01/05/92	7.80			
	4-7 (G/L)	01/06/92				
GLOBULINS BETA	5.6-12.6 (G/L)	01/05/92	10.40			
	7-12 (G/L)	01/06/92				

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1772

(ø) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 5/3 Patient: 138 Treatment: Placebo Sex: Female

			Visit number / Laboratory date			
			Screen		Follow up	
			14/05/92		04/06/92	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
GLOBULINS GAMMA	7.8-19.3 (G/L)	01/05/92	9.80			
	7-15 (G/L)	01/06/92				
TSH	0.2-4 (mIU/L)	01/05/92	5.82			
	0.3-5 (IU/L)	01/06/92				
T4	13-29 (PMOL/L)	01/05/92	17.30			
	50-115 (UG/L)	01/06/92				

1773

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/1 Patient: 151 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 7
			15/01/92	30/01/92
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	14-17 (G/DL)	01/01/91	15.20	15.60
HT	40-54 (X)	01/01/91	46.20	46.80
RBC	4.5-5.7 (10 ⁶ /UL)	01/01/91	4.72	4.95
MBC	5-10 (10 ³ /UL)	01/01/91	7.90	8.50
MBC: N	52-68 (X)	01/01/91	56.00	56.00
MBC: L	26-38 (X)	01/01/91	40.00	34.00
MBC: E	0-5 (X)	01/01/91	1.00	4.00
MBC: M	0-8 (X)	01/01/91	3.00	5.00
MBC: B	0-2 (X)	01/01/91	0.00	1.00
PLATELETS	150-450 (10 ³ /UL)	01/01/91	242.00	238.00
NA+	135-145 (MEQ/L)	01/01/91	144.00	140.00
K+	3.5-5 (MEQ/L)	01/01/91	4.00	5.20
CL-	92-105 (MEQ/L)	01/01/91	100.00	103.00
Ca ⁺⁺	90-100 (MG/L)	01/01/91	96.00	89.00
PO ₄ ⁻⁻	25-50 (MG/L)	01/01/91	47.00	40.00
SGOT	5-37 (UI/L)	01/01/91	35.00	44.00
SGPT	5-40 (UI/L)	01/01/91	22.00	30.00
GAMMA GT	11-43 (UI/L)	01/01/91	92.00	86.00
LDH	200-480 (UI/L)	01/01/91	395.00	242.00
ALK. PHOSPH.	100-290 (UI/L)	01/01/91	148.00	66.00
GLUCOSE	0.8-1.1 (G/L)	01/01/91	0.88	0.78
UREA	3.32-8.3 (MMOL/L)	01/01/91	2.15	2.65
CREATININE	79.6-132.7 (UMOL/L)	01/01/91	57.50	61.90
URIC ACID	180-416 (UMOL/L)	01/01/91	245.00	285.00
TOT BILIRUBIN	3-17.1 (UMOL/L)	01/01/91	10.20	3.00
TOT. PROTEINS	65-75 (G/L)	01/01/91	69.00	66.00
ALBUMINE	35-47 (G/L)	01/01/91	40.00	36.50
TOT. CHOLEST.	5.16-7.22 (MMOL/L)	01/01/91	4.41	4.18
TRIGLYCERIDES	0.5-1.71 (MMOL/L)	01/01/91	1.61	0.86
GLOBULINS ALPHA 1	1-3 (G/L)	01/01/91	3.10	2.00
GLOBULINS ALPHA 2	4-9 (G/L)	01/01/91	7.80	8.50
GLOBULINS BETA	7-13 (G/L)	01/01/91	9.20	8.90
GLOBULINS GAMMA	9-14 (G/L)	01/01/91	8.70	9.90
TSH	0.2-3 (UUI/ML)	01/01/91	3.81	>>
T4	8-20 (PG/ML)	01/01/91	9.10	

1774

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/1 Patient: 152 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			19/02/92		16/03/92		11/04/92	
			value	(\emptyset)	value	(\emptyset)	value	(\emptyset)
Laboratory test	Range value	Range date						
HB	14-17 (G/DL)	01/01/91	12.40	<	13.30	<	13.30	<
HT	40-54 (X)	01/01/91	36.60	<	41.20	<	39.60	<
RBC	4.5-5.7 (10 ⁶ /UL)	01/01/91	4.15	<	4.58		4.45	<
WBC	5-10 (10 ³ /UL)	01/01/91	6.80		7.80		5.70	
WBC: N	52-68 (%)	01/01/91	58.00		68.00		62.00	
WBC: L	26-38 (%)	01/01/91	34.00		25.00	<	34.00	
WBC: E	0-5 (%)	01/01/91	5.00		3.00		2.00	
WBC: M	0-8 (%)	01/01/91	3.00		4.00		2.00	
WBC: B	0-2 (%)	01/01/91	0.00		0.00		0.00	
PLATELETS	150-450 (10 ³ /UL)	01/01/91	215.00		216.00		215.00	
NA+	135-145 (MEQ/L)	01/01/91	142.00		144.00		145.00	
K+	3.5-5 (MEQ/L)	01/01/91	3.90		4.00		4.40	
CL-	92-105 (MEQ/L)	01/01/91	101.00		100.00		101.00	
Ca++	90-100 (MG/L)	01/01/91	96.00		98.00		101.00	>
PO4--	25-50 (MG/L)	01/01/91	36.00		36.00		38.00	
SGOT	5-37 (UI/L)	01/01/91	23.00		16.00		23.00	
SGPT	5-40 (UI/L)	01/01/91	22.00		16.00		24.00	
GAMMA GT	11-43 (UI/L)	01/01/91	20.00		16.00		18.00	
LDH	200-480 (UI/L)	01/01/91	263.00		228.00		211.00	
ALK. PHOSPH.	100-290 (UI/L)	01/01/91	158.00		169.00		189.00	
GLUCOSE	0.8-1.1 (G/L)	01/01/91	0.86		0.89		0.90	
UREA	3.32-8.3 (MMOL/L)	01/01/91	6.64		5.47		5.14	
CREATININE	79.6-132.7 (UMOL/L)	01/01/91	79.60		90.20		90.20	
URIC ACID	180-416 (UMOL/L)	01/01/91	321.00		297.00		339.00	
TOT BILIRUBIN	3-17 (UMOL/L)	01/01/91	7.00		4.00		3.00	
TOT. PROTEINS	65-75 (G/L)	01/01/91	67.00		67.00		67.00	
ALBUMINE	35-47 (G/L)	01/01/91	40.10		37.70		34.30	<
TOT. CHOLEST.	5.16-7.22 (MMOL/L)	01/01/91	5.34		5.72		4.61	<
TRIGLYCERIDES	0.5-1.71 (MMOL/L)	01/01/91	0.79		1.32		0.95	
GLOBULINS ALPHA 1	1-3 (G/L)	01/01/91	1.80		1.90		2.70	
GLOBULINS ALPHA 2	4-9 (G/L)	01/01/91	7.30		8.50		8.90	
GLOBULINS BETA	7-13 (G/L)	01/01/91	7.50		8.70		9.30	
GLOBULINS GAMMA	9-14 (G/L)	01/01/91	10.00		10.00		11.60	
TSH	0.2-3 (UUI/ML)	01/01/91	0.43					
T4	8-20 (PG/ML)	01/01/91	11.90					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/1 Patient: 153 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/03/91		08/04/91		03/05/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-17 (G/DL)	01/01/91	15.40		15.70		15.30	
HT	40-54 (%)	01/01/91	47.00		48.60		46.40	
RBC	4.5-5.7 (10 ⁶ /UL)	01/01/91	5.20		5.36		5.10	
WBC	5-10 (10 ³ /UL)	01/01/91	6.20		9.60		6.50	
WBC: N	52-68 (%)	01/01/91	50.00	<	62.00		63.00	
WBC: L	26-38 (%)	01/01/91	43.00	>	31.00		33.00	
WBC: E	0-5 (%)	01/01/91	5.00		5.00		2.00	
WBC: M	0-8 (%)	01/01/91	2.00		2.00		2.00	
WBC: B	0-2 (%)	01/01/91	0.00		0.00		0.00	
PLATELETS	150-450 (10 ³ /UL)	01/01/91	210.00		208.00		200.00	
NA+	135-145 (MEQ/L)	01/01/91	140.00		140.00		139.00	
K+	3.5-5 (MEQ/L)	01/01/91	3.80		4.20		3.40 <	
CL-	92-105 (MEQ/L)	01/01/91	96.00		101.00		101.00	
Ca++	90-100 (MG/L)	01/01/91	96.00		99.00		99.00	
PO4--	25-50 (MG/L)	01/01/91	30.00		38.00		42.00	
SGOT	5-37 (UI/L)	01/01/91	20.00		31.00		19.00	
SGPT	5-40 (UI/L)	01/01/91	22.00		32.00		19.00	
GAMMA GT	11-43 (UI/L)	01/01/91	20.00		29.00		26.00	
LDH	200-480 (UI/L)	01/01/91	265.00		245.00		239.00	
ALK. PHOSPH.	100-290 (UI/L)	01/01/91	135.00		130.00		131.00	
GLUCOSE	0.8-1.1 (G/L)	01/01/91	0.95		1.07		0.77 <	
UREA	3.32-8.3 (MMOL/L)	01/01/91	3.65		6.80		5.31	
CREATININE	79.6-132.7 (UMOL/L)	01/01/91	78.60	<	81.40		83.20	
URIC ACID	180-416 (UMOL/L)	01/01/91	297.00		297.00		339.00	
TOT. BILIRUBIN	3-17.1 (UMOL/L)	01/01/91	13.20		15.40		10.00	
TOT. PROTEINS	65-75 (G/L)	01/01/91	64.00	<	69.00		68.00	
ALBUMINE	35-47 (G/L)	01/01/91	40.50		42.10		39.00	
TOT. CHOLEST.	5.16-7.22 (MMOL/L)	01/01/91	3.89	<	4.18	<	3.94 <	
TRIGLYCERIDES	0.5-1.71 (MMOL/L)	01/01/91	1.22		1.34		0.87	
GLOBULINS ALPHA 1	1-3 (G/L)	01/01/91	1.40		2.20		2.20	
GLOBULINS ALPHA 2	4-9 (G/L)	01/01/91	4.20		4.90		5.10	
GLOBULINS BETA	7-13 (G/L)	01/01/91	6.40	<	7.70		8.30	
GLOBULINS GAMMA	9-14 (G/L)	01/01/91	11.40		12.00		13.20	
TSH	0.2-3 (UUI/ML)	01/01/91	1.65					
T4	8-20 (PG/ML)	01/01/91	14.20					

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/1 Patient: 154 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	
			25/03/92	
			value	(c)
Laboratory test	Range value	Range date		
HB	14-17 (G/DL)	01/01/91	12.80	<
HT	40-54 (X)	01/01/91	36.90	<
RBC	4.5-5.7 (10 ⁶ /UL)	01/01/91	4.48	<
WBC	5-10 (10 ³ /UL)	01/01/91	7.30	
WBC: N	52-68 (X)	01/01/91	45.00	<
WBC: L	26-38 (X)	01/01/91	49.00	>
WBC: E	0-5 (X)	01/01/91	4.00	
WBC: M	0-8 (X)	01/01/91	2.00	
WBC: B	0-2 (X)	01/01/91	0.00	
PLATELETS	150-450 (10 ³ /UL)	01/01/91	246.00	
NA+	135-145 (MEQ/L)	01/01/91	141.00	
K+	3.5-5 (MEQ/L)	01/01/91	4.30	
CL-	92-105 (MEQ/L)	01/01/91	102.00	
Ca ⁺⁺	90-100 (MG/L)	01/01/91	100.00	
PO ₄ ⁻⁻	25-50 (MG/L)	01/01/91	35.00	
SGOT	5-37 (UI/L)	01/01/91	19.00	
SGPT	5-40 (UI/L)	01/01/91	14.00	
GAMMA GT	11-43 (UI/L)	01/01/91	14.00	
IDH	200-480 (UI/L)	01/01/91	267.00	
ALK. PHOSPH.	100-290 (UI/L)	01/01/91	106.00	
GLUCOSE	0.8-1.1 (G/L)	01/01/91	0.94	
UREA	3.32-8.3 (MMOL/L)	01/01/91	4.64	
CREATININE	79.6-132.7 (UMOL/L)	01/01/91	80.50	
URIC ACID	180-416 (UMOL/L)	01/01/91	196.00	
TOT BILIRUBIN	3-17 (UMOL/L)	01/01/91	4.00	
TOT. PROTEINS	65-75 (G/L)	01/01/91	68.00	
ALBUMINE	35-47 (G/L)	01/01/91	39.50	
TOT. CHOLEST.	5.16-7.22 (MMOL/L)	01/01/91	4.64	<
TRIGLYCERIDES	0.5-1.71 (MMOL/L)	01/01/91	0.39	<
GLOBULINS ALPHA 1	1-3 (G/L)	01/01/91	2.40	
GLOBULINS ALPHA 2	4-9 (G/L)	01/01/91	7.70	
GLOBULINS BETA	7-13 (G/L)	01/01/91	7.80	
GLOBULINS GAMMA	9-14 (G/L)	01/01/91	10.40	
TSH	0.2-3 (UUI/ML)	01/01/91	4.20	>>
T4	8-20 (PG/ML)	01/01/91	11.30	

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/1 Patient: 155 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 28	
			02/07/92		30/07/92		06/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-17 (G/DL)	01/07/92	16.40		14.70			
	14-18 (G/DL)	01/08/92				13.90	<	
HT	40-54 (X)	01/07/92	49.60		45.10			
	42-52 (X)	01/08/92				41.00	<	
RBC	4.5-5.7 (10 ⁶ /UL)	01/07/92	5.08		4.58			
	4.7-5.1 (10 ⁶ /UL)	01/08/92				4.27	<	
WBC	5-10 (10 ³ /UL)	01/07/92	8.20		5.80			
	4.8-10.8 (10 ³ /UL)	01/08/92				7.90		
WBC: N	52-68 (X)	01/07/92	55.00		55.00			
	42-75 (X)	01/08/92				58.00		
WBC: L	26-38 (X)	01/07/92	42.00	>	38.00			
	20-50 (X)	01/08/92				33.10		
WBC: E	0-5 (X)	01/07/92	2.00		2.00			
	0-10 (X)	01/08/92				0.40		
WBC: M	0-8 (X)	01/07/92	1.00		5.00			
	0-9.3 (X)	01/08/92				2.90		
WBC: B	0-2 (X)	01/07/92	0.00		0.00			
	0-0.2 (X)	01/08/92				0.40	>>	
PLATELETS	150-450 (10 ³ /UL)	01/07/92	237.00		214.00			
	130-400 (10 ³ /UL)	01/08/92				217.00		
NA+	135-145 (MEQ/L)	01/07/92	140.00		144.00			
	135-145 (MMOL/L)	01/08/92				143.00		
K+	3.5-5 (MEQ/L)	01/07/92	4.30		4.10			
	3.6-5 (MMOL/L)	01/08/92				4.00		
CL-	92-105 (MEQ/L)	01/07/92	98.00		101.00			
	97-107 (MMOL/L)	01/08/92				103.00		
Ca++	2.2-2.62 (MMOL/L)	01/07/92	2.57		2.62			
	2.2-2.6 (MMOL/L)	01/08/92				2.50		
PO4--	0.8-1.61 (MMOL/L)	01/07/92	1.16		1.00			
	0.8-1.3 (MMOL/L)	01/08/92				1.16		
SGOT	5-37 (UI/L)	01/07/92	20.00		23.00			
	5-25 (UI/L)	01/08/92				11.00		
SGPT	5-40 (UI/L)	01/07/92	15.00		17.00			
	5-27 (UI/L)	01/08/92				10.00		
GAMMA GT	11-43 (UI/L)	01/07/92	27.00		17.00			
	5-35 (UI/L)	01/08/92				7.00		
LDH	200-480 (UI/L)	01/07/92	269.00		276.00			
ALK. PHOSPH.	100-290 (UI/L)	01/07/92	122.00		102.00			
	60-220 (UI/L)	01/08/92				43.00	<	
GLUCOSE	4.44-6.1 (MMOL/L)	01/07/92	5.99		5.05			
	3.6-5.8 (MMOL/L)	01/08/92				4.30		
UREA	3.32-8.3 (MMOL/L)	01/07/92	6.97		4.81			
	2-8 (MMOL/L)	01/08/92				6.80		
CREATININE	79.6-132.7 (UMOL/L)	01/07/92	95.50		106.20			
	45-110 (UMOL/L)	01/08/92				97.00		
URIC ACID	180-416 (UMOL/L)	01/07/92	392.00		559.00	>>		
	200-400 (UMOL/L)	01/08/92				636.00	>>	
TOT. BILIRUBIN	3-17.1 (UMOL/L)	01/07/92	10.20		8.50			
	2-17 (UMOL/L)	01/08/92				7.00		
TOT. PROTEINS	65-75 (G/L)	01/07/92	76.00	>	71.00			
	60-75 (G/L)	01/08/92				65.00		
ALBUMINE	35-47 (G/L)	01/07/92	42.20		42.60			
	35-55 (G/L)	01/08/92				40.20		
TOT. CHOLEST.	5.16-7.22 (MMOL/L)	01/07/92	6.94		6.47			
TRIGLYCERIDES	0.5-1.71 (MMOL/L)	01/07/92	0.86		1.04			
GLOBULINS ALPHA 1	1-3 (G/L)	01/07/92	2.50		2.10			
	3-5 (X)	01/08/92				4.40		
GLOBULINS ALPHA 2	4-9 (G/L)	01/07/92	8.40		7.20			
	6-10 (X)	01/08/92				6.60		
GLOBULINS BETA	7-13 (G/L)	01/07/92	10.10		8.20			
	10-15 (X)	01/08/92				12.20		

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/1 Patient: 155 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 28	
			02/07/92		30/07/92		06/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
GLOBULINS GAMMA	9-14 (G/L)	01/07/92	12.60		10.70			
	12-20 (%)	01/08/92				16.00		
TSH	0.2-3 (UUI/ML)	01/07/92	0.92					
T4	8-20 (PG/ML)	01/07/92	10.50					

1779

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/1 Patient: 156 Treatment: Placebo Sex: Female

			Visit number / Laboratory date	
			Screen	
			03/09/92	
			value	(*)
Laboratory test	Range value	Range date		
HB	14-17 (G/DL)	01/01/91	12.70	<
HT	40-54 (%)	01/01/91	37.90	<
RBC	4.5-5.7 (10 ⁶ /UL)	01/01/91	4.26	<
WBC	5-10 (10 ³ /UL)	01/01/91	10.10	>
WBC: N	52-68 (%)	01/01/91	53.00	
WBC: L	26-38 (%)	01/01/91	42.00	>
WBC: E	0-5 (%)	01/01/91	4.00	
WBC: M	0-8 (%)	01/01/91	1.00	
WBC: B	0-2 (%)	01/01/91	0.00	
PLATELETS	150-450 (10 ³ /UL)	01/01/91	301.00	
NA+	135-145 (MEQ/L)	01/01/91	140.00	
K+	3.5-5 (MEQ/L)	01/01/91	4.10	
CL-	92-105 (MEQ/L)	01/01/91	102.00	
Ca++	90-100 (MG/L)	01/01/91	95.00	
PO4--	25-50 (MG/L)	01/01/91	27.00	
SGOT	5-37 (UI/L)	01/01/91	22.00	
SGPT	5-40 (UI/L)	01/01/91	36.00	
GAMMA GT	11-43 (UI/L)	01/01/91	46.00	>
LDH	200-480 (UI/L)	01/01/91	278.00	
ALK. PHOSPH.	100-290 (UI/L)	01/01/91	63.00	<
GLUCOSE	0.8-1.1 (G/L)	01/01/91	1.05	
UREA	3.32-8.3 (MMOL/L)	01/01/91	7.80	
CREATININE	79.6-132.7 (UMOL/L)	01/01/91	67.20	<
URIC ACID	180-416 (UMOL/L)	01/01/91	208.00	
TOT BILIRUBIN	3-17 (UMOL/L)	01/01/91	5.10	
TOT. PROTEINS	65-75 (G/L)	01/01/91	63.00	<
ALBUMINE	35-47 (G/L)	01/01/91	35.40	
TOT. CHOLEST.	5.16-7.22 (MMOL/L)	01/01/91	5.05	<
TRIGLYCERIDES	0.5-1.71 (MMOL/L)	01/01/91	1.02	
GLOBULINE ALPHA 1	1-3 (G/L)	01/01/91	2.00	
GLOBULINS ALPHA 2	4-9 (G/L)	01/01/91	9.30	>
GLOBULINS BETA	7-13 (G/L)	01/01/91	8.70	
GLOBULINS GAMMA	9-14 (G/L)	01/01/91	7.40	<
TSH	0.2-3 (UUI/ML)	01/01/91	2.03	
T4	8-20 (PG/ML)	01/01/91	8.50	

1780

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value and laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/2 Patient: 157 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/04/91		21/05/91		10/06/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-15 (G/DL)	01/04/91	16.50	>	15.40	>	16.20	>
HT	35-55 (X)	01/04/91	46.40		43.70		45.20	
RBC	4.5-5.5 (10 ⁶ /UL)	01/04/91	5.20		4.92		5.10	
MBC	4-10 (10 ³ /UL)	01/04/91	5.60		6.30		6.10	
MBC: N	50-75 (X)	01/04/91	57.00		57.00		57.00	
MBC: L	25-40 (X)	01/04/91	41.00	>	38.00		39.00	
MBC: E	1-3 (X)	01/04/91	0.00	<	3.00		0.00	<
MBC: M	2-10 (X)	01/04/91	2.00		2.00		2.00	
MBC: B	0-1 (X)	01/04/91	0.00		0.00		2.00	>>
PLATELETS	150-400 (10 ³ /UL)	01/04/91	252.00		286.00		266.00	
NA+	135-145 (MEQ/L)	01/04/91	142.00		140.00		142.00	
K+	3.5-5.5 (MEQ/L)	01/04/91	5.20		3.60		4.20	
CL-	95-105 (MEQ/L)	01/04/91	102.00		100.00		102.00	
Ca++	90-105 (MG/L)	01/04/91	99.00		92.00		93.00	
PO4--	25-40 (MG/L)	01/04/91	34.00		33.00		29.00	
SGOT	5-22 (UI/L)	01/04/91	22.00		21.00		15.00	
SGPT	5-24 (UI/L)	01/04/91	14.00		15.00		12.00	
GAMMA GT	5-28 (UI/L)	01/04/91	11.00		11.00		12.00	
LDH	140-280 (UI/L)	01/04/91	165.00		165.00		177.00	
ALK. PHOSPH.	50-170 (UI/L)	01/04/91	56.00		52.00		74.00	
GLUCOSE	0.7-1.1 (G/L)	01/04/91	1.09		1.04		1.02	
UREA	0.2-0.5 (G/L)	01/04/91	0.32		0.33		0.27	
CREATININE	7-13 (MG/L)	01/04/91	10.10		9.20		9.00	
URIC ACID	30-60 (MG/L)	01/04/91	41.00		25.00	<	37.00	
TOT. BILIRUBIN	3-10 (MG/L)	01/04/91	8.00		6.00		11.00	>
TOT. PROTEINS	60-80 (G/L)	01/04/91	73.00		70.00		72.70	
ALBUMINE	52-67 (X)	01/04/91	74.30	>	57.80		68.00	>
TOT. CHOLEST.	1.2-2.4 (G/L)	01/04/91	2.43	>	2.10		1.98	
TRIGLYCERIDES	0.45-1.5 (G/L)	01/04/91	0.43	<	0.40	<	0.38	<
GLOBULINS ALPHA 1	2.4-4.6 (X)	01/04/91	1.00	<<	3.70		2.70	
GLOBULINS ALPHA 2	6.6-14 (X)	01/04/91	5.30	<	8.50		7.50	
GLOBULINS BETA	9-15 (X)	01/04/91	8.60	<	13.40		8.00	<
GLOBULINS GAMMA	9-21 (X)	01/04/91	10.80		16.60		9.30	
TSH	0.5-4 (UU/ML)	01/04/91	1.26					
T4	5-20 (NG/L)	01/04/91	12.80					

1781

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/2 Patient: 158 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Day 21	Day 42
			17/12/91	10/01/92
Laboratory test	Range value	Range date	value (€)	value (€)
HB	12-14 (G%)	01/11/91	12.90	13.40
HT	37-47 (X)	01/11/91	39.70	41.60
RBC	4.2-5.4 (10 ⁶ /UL)	01/11/91	4.34	4.42
NBC	4000-9000 (/UL)	01/11/91	9100.00 >	6500.00
NBC: N	50-70 (X)	01/11/91	66.00	60.00
NBC: L	25-45 (X)	01/11/91	27.00	31.00
NBC: E	1-3 (X)	01/11/91	3.00	3.00
NBC: M	2-10 (X)	01/11/91	4.00	5.00
NBC: B	0-1 (X)	01/11/91	0.00	1.00
PLATELETS	150-400 (10 ³ /UL)	01/11/91	290.00	292.00
NA+	136-145 (MMOL/L)	01/11/91	138.00	139.00
K+	3.8-4.8 (MMOL/L)	01/11/91	3.80	4.27
CL-	96-108 (MMOL/L)	01/11/91	100.00	100.00
Ca++	95-105 (MG/L)	01/11/91	95.00	98.00
PD4--	30-40 (MG/L)	01/11/91	40.00	44.80 >
SCOT	5-25 (UI/L)	01/11/91	10.00	12.00
SCPT	5-25 (UI/L)	01/11/91	7.00	8.00
GAMMA GT	5-25 (UI/L)	01/11/91	13.00	17.00
LDH	140-280 (UI/L)	01/11/91	187.00	206.00
ALK. PHOSPH.	50-240 (UI/L)	01/11/91	72.00	82.00
GLUCOSE	0.7-1.1 (G/L)	01/11/91	0.84	0.87
UREA	0.15-0.45 (G/L)	01/11/91	0.27	0.35
CREATININE	6-12 (MG/L)	01/11/91	8.30	9.00
URIC ACID	40-60 (MG/L)	01/11/91	31.00 <	35.00 <
TOT BILIRUBIN	1.5-10 (MG/L)	01/11/91	5.00	6.00
TOT. PROTEINS	60-75 (G/L)	01/11/91	66.00	71.00
ALBUMINE	53-63 (G/L)	01/11/91	64.60 >	61.80
TOT. CHOLEST.	1.2-2.6 (G/L)	01/11/91	1.98	2.26
TRIGLYCERIDES	0.6-1.4 (G/L)	01/11/91	0.78	0.73
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/11/91	2.20	1.60
GLOBULINS ALPHA 2	6-12 (X)	01/11/91	10.60	10.50
GLOBULINS BETA	11-17 (X)	01/11/91	11.60	13.10
GLOBULINS GAMMA	11-19 (X)	01/11/91	10.90 <	13.00

1782

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/2 Patient: 159 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/07/91		07/08/91		29/08/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	7.4-11 (G/DL)	01/06/91	16.30 >	17.80 >	16.50 >			
HT	32-52 (X)	01/06/91	47.90	49.40	47.20			
RBC	4-5.7 (10 ⁶ /UL)	01/06/91	5.74 >	5.97 >	5.65			
WBC	4-10 (10 ³ /UL)	01/06/91	9.50	8.90	10.60 >			
WBC: N	2500-6500 (/MM3)	01/06/91	5320.00	5162.00	5300.00			
WBC: L	1500-3500 (/MM3)	01/06/91	3135.00	3026.00	3604.00 >			
WBC: E	50-250 (/MM3)	01/06/91	95.00	0.00 <	742.00 >>			
WBC: M	200-600 (/MM3)	01/06/91	950.00 >>	712.00 >	954.00 >>			
WBC: B	0-100 (/MM3)	01/06/91	0.00	0.00	0.00			
PLATELETS	150000-300000 (/UL)	01/06/91	272000	278000	231000			
NA+	137-150 (MEQ/L)	01/06/91	141.00	141.00	141.00			
K+	3.7-5.2 (MEQ/L)	01/06/91	4.30	3.90	3.80			
CL-	95-104 (MEQ/L)	01/06/91	106.00 >	106.00 >	107.00 >			
Ca++	90-100 (MG/L)	01/06/91	99.00	100.00	100.00			
PO4--	25-42 (MG/L)	01/06/91	42.00	33.00	37.00			
SGOT	8-20 (UI/L)	01/06/91	14.00	16.00	13.00			
SGPT	8-30 (UI/L)	01/06/91	25.00	26.00	17.00			
GAMMA GT	8-30 (UI/L)	01/06/91	22.00	16.00	25.00			
LDH	160-320 (U/L)	01/06/91	146.00 <	199.00	184.00			
ALK. PHOSPH.	30-90 (U/L)	01/06/91	44.00	52.00	45.00			
GLUCOSE	0.7-1.1 (G/L)	01/06/91	0.87	1.10	1.01			
UREA	0.2-0.5 (G/L)	01/06/91	0.29	0.21	0.23			
CREATININE	7-13 (MG/L)	01/06/91	9.00	10.00	9.00			
URIC ACID	30-70 (MG/L)	01/06/91	65.00	62.00	64.00			
TOT BILIRUBIN	1.5-10 (MG/L)	01/06/91	8.00	8.00	9.00			
TOT. PROTEINS	65-80 (G/L)	01/06/91	70.00	74.00	73.00			
ALBUMINE	37-45 (G/L)	01/06/91	44.70	47.50 >	47.90 >			
TOT. CHOLEST.	1.6-2.6 (G/L)	01/06/91	1.89	1.96	1.93			
TRIGLYCERIDES	0.5-1.7 (G/L)	01/06/91	0.84	0.93	0.89			
GLOBULINS ALPHA 1	1-3 (G/L)	01/06/91	2.10	2.40	2.80			
GLOBULINS ALPHA 2	4-7 (G/L)	01/06/91	5.60	6.20	5.70			
GLOBULINS BETA	5-8 (G/L)	01/06/91	8.50 >	8.90 >	7.70			
GLOBULINS GAMMA	8-14 (G/L)	01/06/91	9.10	9.00	8.90			
TSH	0.2-3 (UU/ML)	01/06/91	0.72					
T4	7-19 (NG/L)	01/06/91	14.80					

1783

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/2 Patient: 160 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/11/91		14/12/91		28/01/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	7.4-11 (G/DL)	01/11/91	15.30 >	14.00 >	15.70 >			
HT	32-52 (X)	01/11/91	43.10	41.20	45.50			
RBC	4-5.7 (10 ⁶ /UL)	01/11/91	4.68	4.51	4.75			
WBC	4-10 (10 ³ /UL)	01/11/91	5.90	5.10	7.70			
WBC: N	50-70 (%)	01/11/91	53.00	52.00	63.00			
WBC: L	25-45 (%)	01/11/91	37.00	42.00	34.00			
WBC: E	1-3 (%)	01/11/91	2.00	1.00	0.00 <			
WBC: M	2-9 (%)	01/11/91	8.00	5.00	3.00			
WBC: B	0-1 (%)	01/11/91	0.00	0.00	0.00			
PLATELETS	150000-300000 (/UL)	01/11/91	279000	323000 >				
NA+	137-150 (MEQ/L)	01/11/91	139.00	142.00	139.00			
K+	3.7-5.2 (MEQ/L)	01/11/91	4.50	4.60	4.40			
CL-	95-104 (MEQ/L)	01/11/91	105.00 >	105.00 >	103.00			
Ca++	90-100 (MG/L)	01/11/91	93.00	94.00	90.00			
PO4--	25-42 (MG/L)	01/11/91	35.00	37.00	30.00			
SGOT	8-20 (UI/L)	01/11/91	44.00 >>	34.00 >	32.00 >			
SGPT	8-30 (UI/L)	01/11/91	78.00 >>	71.00 >>	47.00 >			
GAMMA GT	8-30 (UI/L)	01/11/91	45.00 >	42.00 >	39.00 >			
LDH	160-320 (U/L)	01/11/91	126.00 <	198.00	213.00			
ALK. PHOSPH.	30-90 (U/L)	01/11/91	28.00 <	59.00	53.00			
GLUCOSE	0.7-1.1 (G/L)	01/11/91	0.94	1.06	1.07			
UREA	0.2-0.5 (G/L)	01/11/91	0.33	0.27	0.31			
CREATININE	7-13 (MG/L)	01/11/91	11.00	13.00	11.00			
URIC ACID	30-70 (MG/L)	01/11/91	76.00 >	69.00	60.00			
TOT BILIRUBIN	1.5-10 (MG/L)	01/11/91	13.00 >	3.00	6.00			
TOT. PROTEINS	65-80 (G/L)	01/11/91	66.00	75.00	69.00			
ALBUMINE	37-45 (G/L)	01/11/91	40.60	47.90 >	40.30			
TOT. CHOLEST.	1.6-2.6 (G/L)	01/11/91	2.23	2.25	2.06			
TRIGLYCERIDES	0.5-1.7 (G/L)	01/11/91	1.48	1.77 >	0.98			
GLOBULINS ALPHA 1	1-3 (G/L)	01/11/91	1.60	2.00	2.20			
GLOBULINS ALPHA 2	4-7 (G/L)	01/11/91	4.40	4.70	5.40			
GLOBULINS BETA	5-8 (G/L)	01/11/91	8.90 >	8.40 >	8.30 >			
GLOBULINS GAMMA	8-14 (G/L)	01/11/91	10.40	12.10	12.80			
TSH	0.2-3 (UU/ML)	01/11/91	0.90					
T4	7-19 (NG/L)	01/11/91	17.30					

1784

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/2 Patient: 161 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			18/02/92		11/03/92	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	12-17 (G/DL)	01/01/92	15.20		14.80	
HT	42-52 (X)	01/01/92	47.10		45.50	
RBC	4.2-5.2 (10 ⁶ /UL)	01/01/92	5.62 >		5.34 >	
MBC	4-10 (10 ³ /UL)	01/01/92	9.20		19.10 >>	
MBC: N	50-75 (X)	01/01/92	38.00 <		63.00	
MBC: L	25-40 (X)	01/01/92	59.00 >>		32.00	
MBC: E	1-3 (X)	01/01/92	1.00		2.00	
MBC: M	2-10 (X)	01/01/92	2.00		8.00	
MBC: B	0-1 (X)	01/01/92	0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/01/92	255.00		285.00	
NA+	135-145 (MEQ/L)	01/01/92	136.00		137.00	
K+	3.5-5.5 (MEQ/L)	01/01/92	4.40		4.40	
CL-	95-105 (MEQ/L)	01/01/92	100.00		98.00	
Ca++	85-105 (MG/L)	01/01/92	88.00		88.00	
PO4--	20-50 (MG/L)	01/01/92	34.00		31.00	
SGOT	7-30 (U/L)	01/01/92	11.00		12.00	
SGPT	10-50 (U/L)	01/01/92	10.00		23.00	
GAMMA GT	5-25 (UI/L)	01/01/92	14.00		18.00	
LDH	150-240 (U/L)	01/01/92	114.00 <		129.00 <	
ALK. PHOSPH.	60-170 (U/L)	01/01/92	67.00		50.00 <	
GLUCOSE	0.7-1.1 (G/L)	01/01/92	0.85		0.90	
UREA	0.2-0.45 (G/L)	01/01/92	0.20		0.19 <	
CREATININE	7-15 (MG/L)	01/01/92	7.70		8.10	
URIC ACID	30-60 (MG/L)	01/01/92	38.00		31.00	
TOT BILIRUBIN	1.5-10 (MG/L)	01/01/92	5.90		5.40	
TOT. PROTEINS	65-75 (G/L)	01/01/92	64.00 <		64.00 <	
ALBUMINE	35-50 (G/L)	01/01/92	37.10		52.70 >	
TOT. CHOLEST.	1.2-2 (G/L)	01/01/92	2.71 >>		2.44 >	
TRIGLYCERIDES	0.4-1.5 (G/L)	01/01/92	0.95		0.75	
GLOBULINS ALPHA 1	3-4 (X)	01/01/92	2.80 <		4.20 >	
GLOBULINS ALPHA 2	9-11 (X)	01/01/92	12.40 >		13.10 >	
GLOBULINS BETA	12-14 (X)	01/01/92	15.00 >		9.80 <	
GLOBULINS GAMMA	12-15 (X)	01/01/92	11.90 <		9.40 <	
TSH	0.1-4 (MUI/L)	01/01/92	1.50			
T4	9.1-21.8 (NG/L)	01/01/92	13.60			

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1785

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/2 Patient: 162 Treatment: Placebo Sex: Male

			Visit number / Laboratory data
			Screen
			08/07/91
			value (o)
Laboratory test	Range value	Range date	
HB	7.4-11 (G/DL)	01/06/91	14.90 >
HT	32-52 (%)	01/06/91	44.20
RBC	4-5.7 (10 ⁶ /UL)	01/06/91	4.94
WBC	4-10 (10 ³ /UL)	01/06/91	9.90
WBC: N	50-70 (%)	01/06/91	67.00
WBC: L	25-45 (%)	01/06/91	24.00 <
WBC: E	1-3 (%)	01/06/91	1.00
WBC: M	2-9 (%)	01/06/91	8.00
WBC: B	0-1 (%)	01/06/91	0.00
PLATELETS	150000-300000 (/UL)	01/06/91	304000 >
NA+	137-150 (MEQ/L)	01/06/91	140.00
K+	3.7-5.2 (MEQ/L)	01/06/91	4.30
CL-	95-104 (MEQ/L)	01/06/91	103.00
Ca++	90-100 (MG/L)	01/06/91	98.00
PO4--	25-42 (MG/L)	01/06/91	30.00
SGOT	8-20 (UI/L)	01/06/91	13.00
SGPT	8-30 (UI/L)	01/06/91	12.00
GAMMA GT	8-30 (UI/L)	01/06/91	19.00
LDH	160-320 (U/L)	01/06/91	159.00 <
ALK. PHOSPH.	30-90 (U/L)	01/06/91	32.00
GLUCOSE	0.7-1.1 (G/L)	01/06/91	0.95
UREA	0.2-0.5 (G/L)	01/06/91	0.35
CREATININE	7-13 (MG/L)	01/06/91	10.00
URIC ACID	30-70 (MG/L)	01/06/91	37.00
TOT BILIRUBIN	1.5-10 (MG/L)	01/06/91	5.00
TOT. PROTEINS	65-80 (G/L)	01/06/91	68.00
ALBUMINE	37-45 (G/L)	01/06/91	42.70
TOT. CHOLEST.	1.6-2.6 (G/L)	01/06/91	1.84
TRIGLYCERIDES	0.5-1.7 (G/L)	01/06/91	0.89
GLOBULINS ALPHA 1	1-3 (G/L)	01/06/91	2.20
GLOBULINS ALPHA 2	4-7 (G/L)	01/06/91	5.60
GLOBULINS BETA	5-8 (G/L)	01/06/91	8.70 >
GLOBULINS GAMMA	8-14 (G/L)	01/06/91	8.80
TSH	0.2-3 (UU/ML)	01/06/91	0.30
T4	7-19 (NG/L)	01/06/91	15.10

1786

(o) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/2 Patient: 169 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			09/12/91		15/01/92	
			value	(c)	value	(e)
Laboratory test	Range value	Range date				
HB	7.4-11 (G/DL)	01/12/91	12.20 >	13.50 >		
HT	32-52 (X)	01/12/91	35.60	41.20		
RBC	4-5.7 (10 ⁶ /UL)	01/12/91	3.78 <	4.39		
WBC	4-10 (10 ³ /UL)	01/12/91	9.70	11.00 >		
WBC: N	50-70 (X)	01/12/91	68.00	68.00		
WBC: L	25-45 (X)	01/12/91	30.00	28.00		
WBC: E	1-3 (X)	01/12/91	1.00	2.00		
WBC: M	2-9 (X)	01/12/91	1.00 <	2.00		
WBC: B	0-1 (X)	01/12/91	0.00	0.00		
PLATELETS	150000-350000 (/UL)	01/12/91	190000	183000		
NA+	137-150 (MEQ/L)	01/12/91	135.00 <	142.00		
K+	3.7-5.2 (MEQ/L)	01/12/91	4.40	4.70		
CL-	100-104 (MEQ/L)	01/12/91	98.00 <	101.00		
Ca++	90-105 (MG/L)	01/12/91	99.00	102.00		
PO4--	30-40 (MG/L)	01/12/91	40.00	30.00		
SGOT	5-18 (UI/L)	01/12/91	19.00 >	15.00		
SGPT	5-15 (UI/L)	01/12/91	6.00	8.00		
GAMMA GT	4-28 (UI/L)	01/12/91	14.00	10.00		
LDH	120-240 (UI/L)	01/12/91	221.00	239.00		
ALK. PHOSPH.	60-170 (UI/L)	01/12/91	99.00	103.00		
GLUCOSE	0.7-1.1 (G/L)	01/12/91	0.91	0.98		
UREA	0.2-0.45 (G/L)	01/12/91	0.38	0.46 >		
CREATININE	5-13 (MG/L)	01/12/91	11.50	11.90		
URIC ACID	40-65 (MG/L)	01/12/91	36.00 <	37.00 <		
TOT. BILIRUBIN	2-10 (MG/L)	01/12/91	8.00	3.00		
TOT. PROTEINS	60-75 (G/L)	01/12/91	63.00	73.00		
ALBUMINE	34-48 (G/L)	01/12/91	41.00	43.20		
TOT. CHOLEST.	1.8-2.6 (G/L)	01/12/91	2.13	2.45		
TRIGLYCERIDES	0.6-1.5 (G/L)	01/12/91	0.47 <	0.88		
GLOBULINS ALPHA 1	1-4 (X)	01/12/91	2.40	3.90		
GLOBULINS ALPHA 2	6-9 (X)	01/12/91	7.10	9.00		
GLOBULINS BETA	10-14 (X)	01/12/91	11.40	12.50		
GLOBULINS GAMMA	13-19 (X)	01/12/91	14.00	15.30		

1787

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/2 Patient: 170 Treatment: Placebo Sex: Male

			Visit number / Laboratory date	
			Screen	
			29/10/91	
			value	(*)
Laboratory test	Range value	Range date		
HB	11-15 (G/DL)	01/10/91	14.20	
HT	42-48 (%)	01/10/91	39.00	<
RBC	4.5-5.5 (10 ⁶ /UL)	01/10/91	4.59	
WBC	5-10 (10 ³ /UL)	01/10/91	5.60	
WBC: N	45-70 (%)	01/10/91	60.00	
WBC: L	20-40 (%)	01/10/91	32.00	
WBC: E	1-2 (%)	01/10/91	3.00	>>
WBC: M	2-8 (%)	01/10/91	3.00	
WBC: B	0-1 (%)	01/10/91	2.00	>>
NA+	135-145 (MMOL/L)	01/10/91	139.00	
K+	3.5-5 (MMOL/L)	01/10/91	4.50	
CL-	95-110 (MMOL/L)	01/10/91	103.00	
Ca++	81-104 (MG/L)	01/10/91	89.00	
PO4--	25-50 (MG/L)	01/10/91	36.00	
SGOT	4-45 (UI/L)	01/10/91	11.00	
SGPT	4-45 (UI/L)	01/10/91	10.00	
GAMMA GT	3-38 (UI/L)	01/10/91	19.00	
LDH	160-320 (UI/L)	01/10/91	262.00	
ALK. PHOSPH.	50-70 (UI/L)	01/10/91	75.00	>
GLUCOSE	0.6-1.1 (G/L)	01/10/91	0.83	
UREA	0.18-0.43 (G/L)	01/10/91	0.22	
CREATININE	0-12 (MG/L)	01/10/91	10.50	
URIC ACID	34-70 (MG/L)	01/10/91	46.00	
TOT BILIRUBIN	1-10 (MG/L)	01/10/91	3.70	
TOT. PROTEINS	62-80 (G/L)	01/10/91	69.00	
ALBUMINE	39-53 (G/L)	01/10/91	42.60	
TOT. CHOLEST.	1.4-2.5 (G/L)	01/10/91	2.55	>
TRIGLYCERIDES	0.5-1.5 (G/L)	01/10/91	1.13	
GLOBULINS ALPHA 1	2-4.5 (%)	01/10/91	1.70	<
GLOBULINS ALPHA 2	10-14 (%)	01/10/91	9.90	<
GLOBULINS BETA	6-13 (%)	01/10/91	12.40	
GLOBULINS GAMMA	10-19 (%)	01/10/91	14.20	
TSH	0.6-4.8 (UU/ML)	01/10/91	1.84	
T4	4.6-12 (UG/DL)	01/10/91	7.70	

1788

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/2 Patient: 171 Treatment: Imipramine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			20/07/92		11/08/92		16/09/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/92	12.60		12.50		12.20	
HT	37-47 (%)	01/06/92	38.60		38.10		37.40	
RBC	4-5.4 (10 ⁶ /UL)	01/06/92	4.11		4.07		3.99 <	
WBC	5-10 (10 ³ /UL)	01/06/92	6.00		6.10		4.60 <	
WBC: N	45-70 (%)	01/06/92	60.90		67.36		56.21	
WBC: L	20-40 (%)	01/06/92	31.28		25.19		35.17	
WBC: E	1-2 (%)	01/06/92	1.32		1.01		1.29	
WBC: M	2-8 (%)	01/06/92	5.98		5.93		6.55	
WBC: B	0-1 (%)	01/06/92	0.52		0.50		0.78	
PLATELETS	150-450 (10 ³ /UL)	01/06/92	245.00		247.00		252.00	
NA+	132-145 (MEQ/L)	01/06/92	144.00		141.00		143.00	
K+	3.8-5.2 (MEQ/L)	01/06/92	4.00		4.00		4.10	
CL-	90-110 (MEQ/L)	01/06/92	102.00		107.00		106.00	
Ca++	88-102 (MG/L)	01/06/92	99.00		95.00		94.00	
PO4--	25-47 (MG/L)	01/06/92	42.00		37.00		38.00	
SGOT	5-25 (UI/L)	01/06/92	17.00		20.00		20.00	
SGPT	5-22 (UI/L)	01/06/92	13.00		21.00		30.00 >	
GAMMA GT	5-25 (UI/L)	01/06/92	5.00		12.00		14.00	
LDH	140-280 (UI/L)	01/06/92	181.00		202.00		229.00	
ALK. PHOSPH.	30-90 (UI/L)	01/06/92	50.00		61.00		62.00	
GLUCOSE	0.6-1.1 (G/L)	01/06/92	1.00		0.95		0.95	
UREA	0.15-0.45 (G/L)	01/06/92	0.34		0.36		0.30	
CREATININE	5-14 (MG/L)	01/06/92	6.30		8.00		9.40	
URIC ACID	20-60 (MG/L)	01/06/92	50.00		47.00		43.00	
TOT BILIRUBIN	2-12 (MG/L)	01/06/92	6.00		6.00		5.00	
TOT. PROTEINS	60-75 (G/L)	01/06/92	68.00		67.00		66.00	
ALBUMINE	52-65 (%)	01/06/92	57.70		65.50 >		61.70	
TOT. CHOLEST.	1.5-2.6 (G/L)	01/06/92	2.09		1.86		2.09	
TRIGLYCERIDES	0.4-1.5 (G/L)	01/06/92	0.52		0.43		0.43	
GLOBULINS ALPHA 1	1.2-5 (%)	01/06/92	6.00 >		2.30		4.50	
GLOBULINS ALPHA 2	6-12 (%)	01/06/92	11.70		9.80		11.20	
GLOBULINS BETA	11-17 (%)	01/06/92	15.10		11.30		9.40 <	
GLOBULINS GAMMA	11-20 (%)	01/06/92	9.50 <		11.10		13.20	
TSH	0.32-5 (UU/NL)	01/06/92	0.80					
T4	4.5-12 (UG/DL)	01/06/92	6.60					

1789

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value and laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/2 Patient: 172 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/07/92		27/07/92		22/08/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12-14 (G/DL)	01/07/92	10.70	<	12.50		11.90 <	
HT	37-47 (X)	01/07/92	32.90	<	35.30	<		
	34-47 (X)	01/08/92					34.70	
RBC	4.2-5.4 (10 ⁶ /UL)	01/07/92	3.56	<<	3.90	<	3.85 <	
HBC	4-9 (10 ³ /UL)	01/07/92	4.60		4.85		3.60 <	
HBC: N	45-70 (X)	01/07/92	73.00	>	63.00		59.00	
HBC: L	20-40 (X)	01/07/92	21.00		27.00		33.00	
HBC: E	1-2 (X)	01/07/92	1.00		2.00		2.00	
HBC: M	2-8 (X)	01/07/92	5.00		7.00		5.00	
HBC: B	0-1 (X)	01/07/92	0.00		1.00		1.00	
PLATELETS	150-500 (10 ³ /UL)	01/07/92	269.00		231.00			
	150-450 (10 ³ /UL)	01/08/92					259.00	
NA+	136-145 (MMOL/L)	01/07/92	136.00		140.00			
	135-145 (MMOL/L)	01/08/92					144.00	
K+	3.8-4.8 (MMOL/L)	01/07/92	4.40		3.90			
	3.5-5 (MMOL/L)	01/08/92					4.80	
CL-	96-108 (MMOL/L)	01/07/92	101.00		104.00			
	95-107 (MMOL/L)	01/08/92					106.00	
Ca++	95-105 (MG/L)	01/07/92	99.00		99.00		95.00	
PO4--	30-40 (MG/L)	01/07/92	42.00	>	35.00			
	25-51 (MG/L)	01/08/92					29.00	
SODT	5-25 (UI/L)	01/07/92	10.00		10.00			
	5-21 (UI)	01/08/92					12.00	
SGPT	5-25 (UI/L)	01/07/92	9.00		9.00			
	5-22 (UI)	01/08/92					11.00	
GAMMA GT	5-25 (UI/L)	01/07/92	20.00		21.00		11.00	
LDH	140-280 (UI/L)	01/07/92	250.00		221.00			
	150-320 (UI/L)	01/08/92					187.00	
ALK. PHOSPH.	50-240 (UI/L)	01/07/92	76.00		85.00			
	73-207 (MU/ML)	01/08/92					59.00 <	
GLUCOSE	0.7-1.1 (G/L)	01/07/92	0.88		0.86			
	0.7-1.15 (G/L)	01/08/92					0.72	
UREA	0.15-0.45 (G/L)	01/07/92	0.44		0.38		0.35	
CREATININE	6-12 (MG/L)	01/07/92	12.00		11.00			
	5-13 (MG/L)	01/08/92					10.00	
URIC ACID	40-60 (MG/L)	01/07/92	43.00		28.00	<		
	30-70 (MG/L)	01/08/92					36.00	
TOT BILIRUBIN	3-10 (MG/L)	01/07/92	4.00		4.00			
	1.5-10 (MG/L)	01/08/92					3.40	
DIR BILIRUBIN	0-2.5 (MG/L)	01/08/92					0.60	
TOT. PROTEINS	62-76 (G/L)	01/07/92	74.00		71.00			
	65-75 (G/L)	01/08/92					66.00	
ALBUMINE	53-63 (X)	01/07/92	50.20	<	63.20	>		
	58-67 (X)	01/08/92					68.10 >	
TOT. CHOLEST.	1.2-2.6 (G/L)	01/07/92	2.64	>	2.59		2.13	
TRIGLYCERIDES	0.6-1.4 (G/L)	01/07/92	0.61		0.54	<		
	0.1-1.9 (G/L)	01/08/92					0.58	
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/07/92	3.80		2.10			
	2-4 (X)	01/08/92					2.50	
GLOBULINS ALPHA 2	6-12 (X)	01/07/92	15.10	>	9.00			
	6-10 (X)	01/08/92					5.80 <	
GLOBULINS BETA	5-17 (X)	01/07/92	15.90		13.30			
	8-13.5 (X)	01/08/92					11.10	
GLOBULINS GAMMA	8-19 (X)	01/07/92	14.90		12.40			
	12-19 (X)	01/08/92					12.50	
TSH	0.4-5 (UU/ML)	01/07/92	2.30		2.00			
T4	4.5-12 (UG/DL)	01/07/92	6.50		5.70			

1790

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/2 Patient: 173 Treatment: Placebo Sex: Male

			Visit number / Laboratory date	
			Screen	Day 21
			26/06/92	25/07/92
			value (c)	value (c)
Laboratory test	Range value	Range date		
HB	13-17 (G/DL)	01/06/92	15.80	15.40
HT	40-54 (X)	01/06/92	46.20	45.20
RBC	4.5-5.8 (10 ⁶ /UL)	01/06/92	4.90	4.74
MBC	4-10 (10 ³ /UL)	01/06/92	4.90	5.20
MBC: N	45-70 (X)	01/06/92	52.00	53.00
MBC: L	20-40 (X)	01/06/92	43.00 >	42.00 >
MBC: E	1-2 (X)	01/06/92	2.00	0.00 <
MBC: M	2-8 (X)	01/06/92	2.00	5.00
MBC: B	0-1 (X)	01/06/92	1.00	0.00
PLATELETS	150-400 (10 ³ /UL)	01/06/92	238.00	178.00
NA+	135-145 (MEQ/L)	01/06/92	138.00	140.00
K+	3.8-4.6 (MEQ/L)	01/06/92	4.00	4.00
CL-	95-110 (MEQ/L)	01/06/92	103.00	104.00
Ca++	88-102 (MG/L)	01/06/92	93.00	93.00
PO4--	25-40 (MG/L)	01/06/92	44.00 >	26.00
SGOT	7-25 (UI/L)	01/06/92	15.00	11.00
SGPT	7-30 (UI/L)	01/06/92	25.00	17.00
GAMMA GT	8-38 (UI/L)	01/06/92	22.00	24.00
LDH	140-330 (UI/L)	01/06/92	261.00	134.00 <
ALK. PHOSPH.	30-100 (UI/L)	01/06/92	53.00	48.00
GLUCOSE	0.7-1.1 (G/L)	01/06/92	1.08	0.91
UREA	0.15-0.45 (G/L)	01/06/92	0.34	0.28
CREATININE	5-13 (MG/L)	01/06/92	14.10 >	14.70 >
URIC ACID	25-70 (MG/L)	01/06/92	43.00	50.00
TOT BILIRUBIN	1.5-10 (MG/L)	01/06/92	5.40	5.50
TOT. PROTEINS	60-80 (G/L)	01/06/92	72.00	69.00
ALBUMINE	57-67 (X)	01/06/92	58.90	66.80
TOT. CHOLEST.	1.2-2.4 (G/L)	01/06/92	2.56 >	2.23
TRIGLYCERIDES	0.5-1.5 (G/L)	01/06/92	0.81	0.63
GLOBULINS ALPHA 1	2-4 (X)	01/06/92	3.60	2.90
GLOBULINS ALPHA 2	6-10 (X)	01/06/92	8.30	7.20
GLOBULINS BETA	8-12 (X)	01/06/92	15.00 >	11.80
GLOBULINS GAMMA	12-20 (X)	01/06/92	14.20	11.30 <
TSH	0.24-4 (MUI/L)	01/06/92	1.25	
T4	0.78-1.95 (NG/DL)	01/06/92	1.10	

1791

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/2 Patient: 174 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/05/92		01/06/92		27/06/92	
			value	(†)	value	(†)	value	(†)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/04/92	15.90		15.20		16.00	
HT	33-52 (X)	01/04/92	45.80		45.40		47.40	
RBC	4-5.7 (10 ⁶ /UL)	01/04/92	5.11		4.95		5.23	
WBC	4-10 (10 ³ /UL)	01/04/92	6.00		5.90		7.30	
WBC: N	45-70 (X)	01/04/92	61.00		55.00		64.00	
WBC: L	20-40 (X)	01/04/92	34.00		38.00		30.00	
WBC: E	1-2 (X)	01/04/92	0.00	<	0.00	<	0.00	
WBC: M	2-8 (X)	01/04/92	5.00		7.00		6.00	
WBC: B	0-1 (X)	01/04/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	01/04/92	266.00		266.00		275.00	
NA+	135-145 (MEQ/L)	01/04/92	144.00		142.00		144.00	
K+	3.7-5.2 (MEQ/L)	01/04/92	3.80		4.00		4.00	
CL-	95-105 (MEQ/L)	01/04/92	107.00	>	106.00	>	108.00	
Ca ⁺⁺	85-105 (MG/L)	01/04/92	87.00		86.00		86.00	
PO4 ⁻⁻⁻	25-45 (MG/L)	01/04/92	22.00	<	34.00		30.00	
SGOT	6-30 (UI/L)	01/04/92	11.00		8.00		8.00	
SGPT	5-45 (UI/L)	01/04/92	18.00		15.00		17.00	
GAMMA GT	5-38 (UI/L)	01/04/92	21.00		19.00		18.00	
LDH	140-280 (UI/L)	01/04/92	172.00		193.00		151.00	
ALK. PHOSPH.	30-100 (UI/L)	01/04/92	67.00		77.00		81.00	
GLUCOSE	0.65-1.1 (G/L)	01/04/92	1.15	>	0.92		1.16	
UREA	0.2-0.5 (G/L)	01/04/92	0.45		0.32		0.48	
CREATININE	6-12 (MG/L)	01/04/92	11.00		9.00		10.00	
URIC ACID	20-60 (MG/L)	01/04/92	38.00		46.00		40.00	
TOT. BILIRUBIN	1.5-10 (MG/L)	01/04/92	7.00		8.00		5.00	
TOT. PROTEINS	60-80 (G/L)	01/04/92	70.00		66.00		64.00	
ALBUMINE	32-50 (G/L)	01/04/92	42.20		38.30		37.20	
TOT. CHOLEST.	1.2-2.2 (G/L)	01/04/92	2.05		1.74		1.74	
TRIGLYCERIDES	0.5-1.5 (G/L)	01/04/92	0.98		0.71		0.68	
GLOBULINS ALPHA 1	1.5-4.5 (X)	01/04/92	1.90		1.80		2.60	
GLOBULINS ALPHA 2	6-12 (X)	01/04/92	8.10		7.60		8.50	
GLOBULINS BETA	11-17 (X)	01/04/92	12.10		13.60		13.30	
GLOBULINS GAMMA	11-19 (X)	01/04/92	17.50		18.90		17.40	
TSH	0.45-5 (UU/ML)	01/04/92	0.90					
T4	5-12 (UG/DL)	01/04/92	4.70	<				

1792

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 163 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date
			Screen
			05/06/91
			value (⊕)
Laboratory test	Range value	Range date	
HB	13-17 (G/DL)	01/05/91	13.50
HT	40-54 (X)	01/05/91	42.00
RBC	4500000-5500000 (/MM3)	01/05/91	4640000
WBC	5000-10000 (/MM3)	01/05/91	6400.00
WBC: N	50-70 (X)	01/05/91	55.80
WBC: L	25-40 (X)	01/05/91	30.50
WBC: E	1-4 (X)	01/05/91	7.20 >>
WBC: M	4-8 (X)	01/05/91	6.00
WBC: B	0-2 (X)	01/05/91	0.50
PLATELETS	150000-400000 (/MM3)	01/05/91	288000
NA+	135-145 (MEQ/L)	01/05/91	140.00
K+	3.5-4.5 (MEQ/L)	01/05/91	4.20
CL-	95-105 (MEQ/L)	01/05/91	100.00
Ca++	88-104 (MG/L)	01/05/91	93.00
PO4--	25-45 (MG/L)	01/05/91	25.00
SGOT	5-35 (UI/L)	01/05/91	12.00
SGPT	5-35 (UI/L)	01/05/91	13.00
GAMMA GT	5-40 (UI/L)	01/05/91	10.00
LDH	140-330 (UI/L)	01/05/91	278.00
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	79.00
GLUCOSE	0.8-1.1 (G/L)	01/05/91	1.00
UREA	0.15-0.5 (G/L)	01/05/91	0.20
CREATININE	6-12 (MG/L)	01/05/91	14.80 >
URIC ACID	20-60 (MG/L)	01/05/91	49.00
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	3.00
TOT. PROTEINS	60-80 (G/L)	01/05/91	71.00
ALBUMINE	37-42 (G/L)	01/05/91	45.90 >
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	2.29
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	0.86
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	2.06
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	3.98 <
GLOBULINS BETA	5-8 (G/L)	01/05/91	6.96
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	12.10 >
TSH	0.15-3.2 (UUI/ML)	01/05/91	0.68
T4	7-18 (PG/ML)	01/05/91	12.00

1793

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 164 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/10/91		31/10/91		22/11/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-17 (G/DL)	01/05/91	15.50		16.00		15.40	
HT	40-54 (X)	01/05/91	48.00		49.00		46.00	
RBC	4500000-5500000 (/MM3)	01/05/91						
			5500000		5610000 >		5240000	
WBC	5000-10000 (/MM3)	01/05/91	4300.00 <		4300.00 <		3700.00 <	
WBC: N	50-70 (X)	01/05/91	44.40 <		48.90 <		48.50 <	
WBC: L	25-40 (X)	01/05/91	46.20 >		48.00 >		41.30 >	
WBC: E	1-4 (X)	01/05/91	1.80		1.90		2.50	
WBC: M	4-8 (X)	01/05/91	6.80		5.30		6.00	
WBC: B	0-2 (X)	01/05/91	0.80		0.90		1.70	
PLATELETS	150000-400000 (/MM3)	01/05/91						
			252000		295000		261000	
NA+	135-145 (MEQ/L)	01/05/91	140.00		138.00		138.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	3.90		4.60 >		4.30	
CL-	95-105 (MEQ/L)	01/05/91	100.00		95.00		102.00	
Ca++	88-104 (MG/L)	01/05/91	89.00		89.00		88.00	
PO4--	25-45 (MG/L)	01/05/91	28.00		26.00		27.00	
SGOT	5-35 (UI/L)	01/05/91	31.00		32.00		19.00	
SGPT	5-35 (UI/L)	01/05/91	15.00		16.00		37.00 >	
GAMMA GT	5-40 (UI/L)	01/05/91	15.00		20.00		23.00	
LDH	140-330 (UI/L)	01/05/91	304.00		191.00		217.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	81.00		99.00		112.00 <	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.90		0.91		0.78 <	
UREA	0.15-0.5 (G/L)	01/05/91	0.30		0.30		0.36	
CREATININE	6-12 (MG/L)	01/05/91	14.00 >		16.10 >		15.40 >	
URIC ACID	20-60 (MG/L)	01/05/91	58.00 >		58.00 >		61.00 >	
TOT. BILIRUBIN	3-20 (UMOL/L)	01/05/91	5.00		5.00		5.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	72.00		74.00		69.00	
ALBUMINE	37-45 (G/L)	01/05/91	51.20 >		53.10 >		49.40 >	
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	1.76 <		2.00		2.16	
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	0.50		0.49		0.55	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	1.08		1.41		0.96 <	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	4.10		3.85 <		3.66 <	
GLOBULINS BETA	5-8 (G/L)	01/05/91	5.40		5.25		5.52	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	10.20		10.40		9.45	
TSH	0.15-3.2 (UUI/ML)	01/05/91	0.49					
T4	7-18 (PG/ML)	01/05/91	15.10					

1794

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/3 Patient: 165 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/10/91		05/11/91		26/11/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-15 (G/DL)	01/05/91	13.50				12.70	
HT	37-47 (X)	01/05/91	40.00				38.00	
RBC	4000000-5000000 (/MM3)	01/05/91						
			4750000				4490000	
HBC	5000-10000 (/MM3)	01/05/91	7100.00				8700.00	
HBC: N	50-70 (X)	01/05/91	53.80				62.20	
HBC: L	25-40 (X)	01/05/91	38.60				23.60	<
HBC: E	1-4 (X)	01/05/91	0.60	<			6.70	>>
HBC: M	4-8 (X)	01/05/91	6.20				6.60	
HBC: B	0-2 (X)	01/05/91	0.80				0.90	
PLATELETS	150000-400000 (/MM3)	01/05/91						
			278000				351000	
NA+	135-145 (MEQ/L)	01/05/91	139.00		139.00		140.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	3.40	<	3.90		3.80	
CL-	95-105 (MEQ/L)	01/05/91	99.00		97.00		102.00	
Ca++	88-104 (MG/L)	01/05/91	98.00		95.00		96.00	
PO4--	25-45 (MG/L)	01/05/91	27.00		39.00		28.00	
SGOT	5-35 (UI/L)	01/05/91	15.00		22.00		17.00	
SGPT	5-35 (UI/L)	01/05/91	9.00		14.00		43.00	>
GAMMA GT	5-40 (UI/L)	01/05/91	13.00		22.00		184.00	>>
LDH	140-330 (UI/L)	01/05/91	250.00		207.00		279.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	63.00		72.00		276.00	>>
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.90		0.89		0.91	
BUN	()	01/05/91						
UREA	0.15-0.5 (G/L)	01/05/91	0.29		0.36		0.26	
CREATININE	6-12 (MG/L)	01/05/91	9.50		10.40		9.80	
URIC ACID	20-60 (MG/L)	01/05/91	52.00		48.00		42.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	5.00		4.00		3.00	
DIR BILIRUBIN	()	01/05/91						
TOT. PROTEINS	60-80 (G/L)	01/05/91	80.00		75.00		79.00	
ALBUMINE	37-42 (G/L)	01/05/91	54.60	>	50.60	>	52.00	>
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	3.13	>	3.00	>	2.98	>
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	1.01		2.36	>>	1.21	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	2.48		2.03		2.29	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	5.28		5.40		6.79	
GLOBULINS BETA	5-8 (G/L)	01/05/91	8.24	>	7.65		8.45	>
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	9.36		9.38		9.48	
TSH	0.15-3.2 (UUI/ML)	01/05/91	0.57					
T4	7-18 (PG/ML)	01/05/91	15.90					

1795

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 166 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			25/10/91
			value (€)
Laboratory test	Range value	Range date	
HB	11.5-15 (G/DL)	01/05/91	15.00
HT	37-47 (%)	01/05/91	44.00
RBC	4000000-5000000 (/MM3)	01/05/91	4530000
NBC	5000-10000 (/MM3)	01/05/91	12700.0 >
NBC: N	50-70 (%)	01/05/91	66.10
NBC: L	25-40 (%)	01/05/91	24.90 <
NBC: E	1-4 (%)	01/05/91	2.90
NBC: M	4-8 (%)	01/05/91	5.20
NBC: B	0-2 (%)	01/05/91	0.90
PLATELETS	150000-400000 (/MM3)	01/05/91	210000
NA+	135-145 (MEQ/L)	01/05/91	138.00
K+	3.5-4.5 (MEQ/L)	01/05/91	3.40 <
CL-	95-105 (MEQ/L)	01/05/91	100.00
Ca++	88-104 (MG/L)	01/05/91	91.00
PO4--	25-45 (MG/L)	01/05/91	27.00
SGOT	5-35 (UI/L)	01/05/91	26.00
SGPT	5-35 (UI/L)	01/05/91	28.00
GAMMA GT	5-40 (UI/L)	01/05/91	26.00
LDH	140-330 (UI/L)	01/05/91	236.00
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	96.00
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.99
UREA	0.15-0.5 (G/L)	01/05/91	0.38
CREATININE	6-12 (MG/L)	01/05/91	10.30
URIC ACID	20-60 (MG/L)	01/05/91	43.00
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	9.00
TOT. PROTEINS	60-80 (G/L)	01/05/91	69.00
ALBUMINE	37-42 (G/L)	01/05/91	46.40 >
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	2.06
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	1.43
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	2.00
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	5.31
GLOBULINS BETA	5-8 (G/L)	01/05/91	6.49
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	8.76
TSH	0.15-3.2 (UUI/ML)	01/05/91	0.67
T4	7-18 (PG/ML)	01/05/91	13.20

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/3 Patient: 167 Treatment: Placebo Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			14/11/91		09/12/91		27/12/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-15 (G/DL)	01/05/91	13.30		13.90		13.00	
HT	37-47 (X)	01/05/91	39.00		40.50		38.00	
RBC	4000000-5000000 (/MM3)	01/05/91						
			4230000		4430000		4140000	
MBC	5000-10000 (/MM3)	01/05/91	6700.00		5800.00		6100.00	
MBC: N	50-70 (%)	01/05/91	48.00 <		37.00 <		45.30 <	
MBC: L	25-40 (%)	01/05/91	43.10 >		53.90 >>		45.10 >	
MBC: E	1-4 (%)	01/05/91	2.30		2.00		2.40	
MBC: M	4-8 (%)	01/05/91	6.00		6.40		6.50	
MBC: B	0-2 (%)	01/05/91	0.60		0.70		0.70	
PLATELETS	150000-400000 (/MM3)	01/05/91						
			204000		220000		206000	
NA+	135-145 (MEQ/L)	01/05/91	139.00		137.00		136.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	4.00		3.40 <		3.90	
CL-	95-105 (MEQ/L)	01/05/91	98.00		97.00		97.00	
Ca++	88-104 (MG/L)	01/05/91	89.00		93.00		90.00	
PO4--	25-45 (MG/L)	01/05/91	38.00		38.00		34.00	
SGOT	5-35 (UI/L)	01/05/91	26.00		9.00		11.00	
SGPT	5-35 (UI/L)	01/05/91	18.00		15.00		14.00	
GAMMA GT	5-40 (UI/L)	01/05/91	10.00		9.00		13.00	
LDH	140-330 (UI/L)	01/05/91	164.00		174.00		150.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	60.00		70.00		56.00	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.84		0.92		0.92	
UREA	0.15-0.5 (G/L)	01/05/91	0.33		0.26		0.22	
CREATININE	6-12 (MG/L)	01/05/91	9.00		10.30		9.80	
URIC ACID	20-60 (MG/L)	01/05/91	45.00		55.00		50.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	3.00		4.00		3.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	63.00		72.00		67.00	
ALBUMINE	37-42 (G/L)	01/05/91	44.20 >		50.00 >		46.30 >	
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	1.96		1.60 <		1.78 <	
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	0.57		0.67		1.14	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	1.58		1.80		1.81	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	4.03		4.82		4.69	
GLOBULINS BETA	5-8 (G/L)	01/05/91	5.67		6.48		5.90	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	7.56 <		8.86		8.31	
TSH	0.15-3.2 (UUI/ML)	01/05/91	0.89					
T4	7-18 (PG/ML)	01/05/91	14.00					

1797

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 168 Treatment: Placebo Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			26/11/91		23/12/91	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	11.5-15 (G/DL)	01/05/91	12.90		13.60	
HT	37-47 (X)	01/05/91	38.00		40.00	
RBC	4000000-5000000 (/MM3)	01/05/91	4050000		4170000	
WBC	5000-10000 (/MM3)	01/05/91	6000.00		5800.00	
WBC: N	50-70 (%)	01/05/91	52.20		49.40 <	
WBC: L	25-40 (%)	01/05/91	39.00		41.00 >	
WBC: E	1-4 (%)	01/05/91	1.90		3.50	
WBC: M	4-8 (%)	01/05/91	6.30		5.60	
WBC: B	0-2 (%)	01/05/91	0.60		0.50	
PLATELETS	150000-400000 (/MM3)	01/05/91	217000		207000	
NA+	135-145 (MEQ/L)	01/05/91	139.00		140.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	4.20		3.90	
CL-	95-105 (MEQ/L)	01/05/91	100.00		101.00	
Ca++	88-104 (MG/L)	01/05/91	89.00		84.00 <	
PO4--	25-45 (MG/L)	01/05/91	42.00		30.00	
SGOT	5-35 (UI/L)	01/05/91	11.00		10.00	
SGPT	5-35 (UI/L)	01/05/91	10.00		10.00	
GAMMA GT	5-40 (UI/L)	01/05/91	19.00		25.00	
LDH	140-330 (UI/L)	01/05/91	214.00		150.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	47.00 <		38.00 <	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.94		0.82	
UREA	0.15-0.5 (G/L)	01/05/91	0.39		0.23	
CREATININE	6-12 (MG/L)	01/05/91	9.60		7.60	
URIC ACID	20-60 (MG/L)	01/05/91	40.00		47.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	2.00 <		3.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	73.00		67.00	
ALBUMINE	37-42 (G/L)	01/05/91	48.80 >		44.20 >	
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	1.88		1.96	
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	1.82 >		4.52 >>	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	2.99		2.14	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	4.02		4.29	
GLOBULINS BETA	5-8 (G/L)	01/05/91	7.30		7.04	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	9.86		9.31	
TSH	0.15-3.2 (UUI/ML)	01/05/91	1.64			
T4	7-18 (PG/ML)	01/05/91	11.70			

1798

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 505 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 14
			29/11/91	20/12/91
			value (†)	value (†)
Laboratory test	Range value	Range date		
HB	11.5-15 (G/DL)	01/05/91	13.80	14.40
HT	37-47 (X)	01/05/91	40.00	43.00
RBC	4000000-5000000 (/MM3)	01/05/91	4290000	4520000
WBC	5000-10000 (/MM3)	01/05/91	6400.00	8100.00
WBC: N	50-70 (X)	01/05/91	72.00 >	77.50 >
WBC: L	25-40 (X)	01/05/91	22.00 <	14.40 <<
WBC: E	1-4 (X)	01/05/91	1.00	0.50 <
WBC: M	4-8 (X)	01/05/91	4.00	7.10
WBC: B	0-2 (X)	01/05/91	1.00	0.50
PLATELETS	150000-400000 (/MM3)	01/05/91	245000	213000
NA+	135-145 (MEQ/L)	01/05/91	139.00	138.00
K+	3.5-4.5 (MEQ/L)	01/05/91	3.90	3.90
CL-	95-105 (MEQ/L)	01/05/91	101.00	101.00
Ca++	88-104 (MG/L)	01/05/91	92.00	89.00
PO4--	25-45 (MG/L)	01/05/91	28.00	21.00 <<
SGOT	5-35 (UI/L)	01/05/91	16.00	16.00
SGPT	5-35 (UI/L)	01/05/91	18.00	17.00
GAMMA GT	5-40 (UI/L)	01/05/91	10.00	8.00
LDH	140-330 (UI/L)	01/05/91	236.00	214.00
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	62.00	80.00
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.77 <	0.84
UREA	0.15-0.5 (G/L)	01/05/91	0.30	0.19
CREATININE	6-12 (MG/L)	01/05/91	11.30	9.00
URIC ACID	20-60 (MG/L)	01/05/91	44.00	28.00
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	3.00	2.00 <
TOT. PROTEINS	60-80 (G/L)	01/05/91	73.00	69.00
ALBUMINE	37-42 (G/L)	01/05/91	50.70 >	46.90 >
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	2.33	2.03
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	1.33	1.76 >
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	2.19	2.42
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	4.23	4.90
GLOBULINS BETA	5-8 (G/L)	01/05/91	6.79	6.35
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	9.05	8.49
TSH	0.15-3.2 (UUI/ML)	01/05/91	1.13	
T4	7-18 (PG/ML)	01/05/91	12.80	

1799

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 506 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/01/92		29/01/92		19/02/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-15 (G/DL)	01/05/91	13.50		12.50		12.40	
HT	37-47 (X)	01/05/91	42.00		37.00		39.00	
RBC	4000000-5000000 (/MM3)	01/05/91						
			4970000		4500000		4610000	
WBC	5000-10000 (/MM3)	01/05/91	7100.00		6320.00		6060.00	
WBC: N	50-70 (X)	01/05/91	59.10		53.00		59.00	
WBC: L	25-40 (X)	01/05/91	34.40		41.10		36.20	
WBC: E	1-4 (X)	01/05/91	0.40	<	0.20	<	0.30	
WBC: M	4-8 (X)	01/05/91	6.00		5.50		4.30	
WBC: B	0-2 (X)	01/05/91	0.10		0.20		0.20	
PLATELETS	150000-400000 (/MM3)	01/05/91						
			273000		219000		231000	
NA+	135-145 (MEQ/L)	01/05/91	138.00		141.00		141.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	3.80		4.00		3.80	
CL-	95-105 (MEQ/L)	01/05/91	100.00		104.00		104.00	
Ca++	88-104 (MG/L)	01/05/91	90.00		88.00		88.00	
PO4--	25-45 (MG/L)	01/05/91	23.00	<	26.00		20.00	
SGOT	5-35 (UI/L)	01/05/91	17.00		8.00		6.00	
SGPT	5-35 (UI/L)	01/05/91	28.00		14.00		10.00	
GAMMA GT	5-40 (UI/L)	01/05/91	10.00		9.00		8.00	
LDH	140-330 (UI/L)	01/05/91	174.00		144.00		135.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	42.00	<	48.00	<	42.00	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.90		0.96		0.85	
UREA	0.15-0.5 (G/L)	01/05/91	0.35		0.37		0.35	
CREATININE	6-12 (MG/L)	01/05/91	11.10		9.60		10.20	
URIC ACID	20-60 (MG/L)	01/05/91	63.00	>	48.00		53.00	
TOT. BILIRUBIN	3-20 (UMOL/L)	01/05/91	3.00		2.00	<	3.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	71.00		66.00		63.00	
ALBUMINE	37-42 (G/L)	01/05/91	46.90	>	43.50	>	42.70	
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	2.28		2.10		1.89	
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	1.31		0.93		1.24	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	2.49		2.18		1.83	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	5.75		5.54		5.04	
GLOBULINS BETA	5-8 (G/L)	01/05/91	8.17	>	7.79		7.06	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	7.74	<	7.00	<	6.36	
TSH	0.15-3.2 (UUI/ML)	01/05/91	1.73					
T4	7-18 (PG/ML)	01/05/91	13.50					

1800

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 507 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/01/92		04/02/92		24/02/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-15 (G/DL)	01/05/91	13.00		13.60		12.70	
HT	37-47 (%)	01/05/91	39.00		40.00		37.00	
RBC	4000000-5000000 (/MM3)	01/05/91	4450000		4620000		4330000	
HBC	5000-10000 (/MM3)	01/05/91	7300.00		7140.00		5350.00	
HBC: N	50-70 (%)	01/05/91	72.30	>	78.70	>	71.70	
HBC: L	25-40 (%)	01/05/91	19.40	<	14.30	<<	21.90	
HBC: E	1-4 (%)	01/05/91	1.30		1.30		2.20	
HBC: M	4-8 (%)	01/05/91	6.60		5.30		3.60	
HBC: B	0-2 (%)	01/05/91	0.40		0.40		0.60	
PLATELETS	150000-400000 (/MM3)	01/05/91	295000		317000		293000	
NA+	135-145 (MEQ/L)	01/05/91	143.00		138.00		141.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	4.00		3.90		4.40	
CL-	95-105 (MEQ/L)	01/05/91	101.00		99.00		102.00	
Ca++	88-104 (MG/L)	01/05/91	90.00		86.00	<	87.00	
PO4--	25-45 (MG/L)	01/05/91	32.00		36.00		32.00	
SGOT	5-35 (UI/L)	01/05/91	14.00		22.00		21.00	
SGPT	5-35 (UI/L)	01/05/91	35.00		65.00	>	34.00	
GAMMA GT	5-40 (UI/L)	01/05/91	25.00		32.00		36.00	
LDH	140-330 (UI/L)	01/05/91	180.00		208.00		217.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	64.00		74.00		86.00	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.92		0.84		0.98	
UREA	0.15-0.5 (G/L)	01/05/91	0.39		0.33		0.34	
CREATININE	6-12 (MG/L)	01/05/91	7.80		9.80		8.30	
URIC ACID	20-60 (MG/L)	01/05/91	32.00		34.00		28.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	3.00		5.00		2.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	71.00		73.00		70.00	
ALBUMINE	37-42 (G/L)	01/05/91	49.40	>	51.70	>	46.80	
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	2.05		1.99		1.76	
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	0.72		0.74		0.43	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	1.70		1.31		1.68	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	3.76	<	3.29	<	4.27	
GLOBULINS BETA	5-8 (G/L)	01/05/91	6.32		6.50		6.37	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	9.80		10.20		10.90	
TSH	0.15-3.2 (UUI/ML)	01/05/91	0.46					
T4	7-18 (PG/ML)	01/05/91	14.90					

1801

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 508 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/01/92		25/02/92		17/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-15 (G/DL)	01/05/91	13.10		14.30		13.20	
HT	37-47 (%)	01/05/91	41.00		43.00		40.00	
RBC	4000000-5000000 (/MM3)	01/05/91						
			4210000		4480000		4210000	
HBC	5000-10000 (/MM3)	01/05/91	4270.00	<	5460.00		4910.00	
HBC: N	50-70 (%)	01/05/91	63.20		60.90		65.20	
HBC: L	25-40 (%)	01/05/91	30.80		31.30		27.50	
HBC: E	1-4 (%)	01/05/91	1.50		2.40		1.80	
HBC: M	4-8 (%)	01/05/91	3.80	<	4.70		4.70	
HBC: B	0-2 (%)	01/05/91	0.70		0.70		0.80	
PLATELETS	150000-400000 (/MM3)	01/05/91						
			339000		332000		322000	
NA+	135-145 (MEQ/L)	01/05/91	140.00		139.00		140.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	4.30		4.40		4.40	
CL-	95-105 (MEQ/L)	01/05/91	103.00		99.00		102.00	
Ca++	88-104 (MG/L)	01/05/91	88.00		92.00		90.00	
PO4--	25-45 (MG/L)	01/05/91	27.00		32.00		29.00	
SGOT	5-35 (UI/L)	01/05/91	8.00		8.00		8.00	
SGPT	5-35 (UI/L)	01/05/91	13.00		13.00		15.00	
GAMMA GT	5-40 (UI/L)	01/05/91			12.00		11.00	
LDH	140-330 (UI/L)	01/05/91	244.00		206.00		175.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	78.00		90.00		77.00	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	1.05		1.04		0.93	
UREA	0.15-0.5 (G/L)	01/05/91	0.32		0.37		0.26	
CREATININE	6-12 (MG/L)	01/05/91	11.50		11.70		10.40	
URIC ACID	20-60 (MG/L)	01/05/91	45.00		43.00		44.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	3.00		3.00		3.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	70.00		76.00		70.00	
ALBUMINE	37-42 (G/L)	01/05/91	46.30	>	50.90	>	45.40	
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	2.34		2.61	>	2.14	
TRIGLICERIDES	0.25-1.6 (G/L)	01/05/91	0.75		1.00		0.75	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	1.82		2.03		1.82	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	4.90		5.62		4.83	
GLOBULINS BETA	5-8 (G/L)	01/05/91	7.84		8.97	>	8.40	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	9.10		10.50		9.52	
TSH	0.15-3.2 (UUI/ML)	01/05/91	1.01					
T4	7-18 (PG/ML)	01/05/91	16.30					

1802

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 6/3 Patient: 509 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/02/92		16/03/92		06/04/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-17 (G/DL)	01/05/91	17.80	>	17.10	>	17.40	>
HT	40-54 (%)	01/05/91	50.00		51.00		50.00	
RBC	4500000-5500000 (/MM3)	01/05/91						
			5870000	>	5880000	>	5820000	>
WBC	5000-10000 (/MM3)	01/05/91	6270.00		10300.0	>	6510.00	
WBC: N	50-70 (%)	01/05/91	69.10		76.50	>	64.00	
WBC: L	25-40 (%)	01/05/91	20.40	<	13.50	<<	25.50	
WBC: E	1-4 (%)	01/05/91	3.30		3.40		2.70	
WBC: M	4-8 (%)	01/05/91	5.80		5.80		6.80	
WBC: B	0-2 (%)	01/05/91	1.40		0.80		1.00	
PLATELETS	150000-400000 (/MM3)	01/05/91						
			230000		224000		272000	
NA+	135-145 (MEQ/L)	01/05/91	139.00		141.00		142.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	3.70		3.50		3.80	
CL-	95-105 (MEQ/L)	01/05/91	95.00		101.00		100.00	
Ca++	88-104 (MG/L)	01/05/91	89.00		90.00		90.00	
PO4--	25-45 (MG/L)	01/05/91	29.00		27.00		38.00	
SGOT	5-35 (UI/L)	01/05/91	12.00		11.00		12.00	
SGPT	5-35 (UI/L)	01/05/91	10.00		9.00		10.00	
GAMMA GT	5-40 (UI/L)	01/05/91	13.00		14.00		12.00	
LDH	140-330 (UI/L)	01/05/91	140.00		197.00		174.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	49.00	<	57.00		52.00	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.82		0.83		0.85	
UREA	0.15-0.5 (G/L)	01/05/91	0.18		0.25		0.32	
CREATININE	6-12 (MG/L)	01/05/91	11.80		10.90		10.30	
URIC ACID	20-60 (MG/L)	01/05/91	55.00		48.00		56.00	
TOT. BILIRUBIN	3-20 (UMOL/L)	01/05/91	6.00		6.00		8.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	75.00		78.00		78.00	
ALBUMINE	37-42 (G/L)	01/05/91	48.40	>	49.80	>	50.00	>
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	1.38	<	1.31	<	1.47	<
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	0.68		0.68		0.58	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	1.88		1.79		1.79	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	4.20		4.21		3.90	<
GLOBULINS BETA	5-8 (G/L)	01/05/91	6.90		7.49		7.18	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	13.70	>	14.70	>	15.10	>
TSH	0.15-3.2 (UUI/ML)	01/05/91	1.05					
T4	7-18 (PG/ML)	01/05/91	16.90					

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1803

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 510 Treatment: Roboxetine Sex: Female

			Visit number / Laboratory data
			Screen
			26/02/92
			value (c)
Laboratory test	Range value	Range date	
HB	11.5-15 (G/DL)	01/05/91	12.40
HT	37-47 (%)	01/05/91	36.00 <
RBC	4000000-5000000 (/MM3)	01/05/91	4490000
WBC	5000-10000 (/MM3)	01/05/91	5930.00
WBC: N	50-70 (%)	01/05/91	55.60
WBC: L	25-40 (%)	01/05/91	34.00
WBC: E	1-4 (%)	01/05/91	3.70
WBC: M	4-8 (%)	01/05/91	5.80
WBC: B	0-2 (%)	01/05/91	0.90
PLATELETS	150000-400000 (/MM3)	01/05/91	322000
NA+	135-145 (MEQ/L)	01/05/91	138.00
K+	3.5-4.5 (MEQ/L)	01/05/91	4.20
CL-	95-105 (MEQ/L)	01/05/91	100.00
Ca++	88-104 (MG/L)	01/05/91	88.00
PO4--	25-45 (MG/L)	01/05/91	33.00
SGOT	5-35 (UI/L)	01/05/91	10.00
SGPT	5-35 (UI/L)	01/05/91	13.00
GAMMA GT	5-40 (UI/L)	01/05/91	5.00
LDH	140-330 (UI/L)	01/05/91	203.00
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	61.00
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.63 <
UREA	0.15-0.5 (G/L)	01/05/91	0.29
CREATININE	6-12 (MG/L)	01/05/91	9.00
URIC ACID	20-60 (MG/L)	01/05/91	40.00
TOT. BILIRUBIN	3-20 (UMOL/L)	01/05/91	2.00 <
TOT. PROTEINS	60-80 (G/L)	01/05/91	76.00
ALBUMINE	37-42 (G/L)	01/05/91	48.30 >
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	1.98
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	0.90
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	2.05
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	6.31
GLOBULINS BETA	5-8 (G/L)	01/05/91	7.45
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	11.90
TSH	0.15-3.2 (UUI/ML)	01/05/91	1.24
T4	7-18 (PG/ML)	01/05/91	14.00

1804

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 511 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			19/03/92	07/04/92
			value (€)	value (¢)
Laboratory test	Range value	Range date		
HB	11.5-15 (G/DL)	01/05/91	13.50	14.20
HT	37-47 (X)	01/05/91	40.00	42.00
RBC	4000000-5000000 (/MM3)	01/05/91	4610000	4690000
MBC	5000-10000 (/MM3)	01/05/91	5810.00	4610.00 <
MBC: N	50-70 (X)	01/05/91	55.70	50.20
MBC: L	25-40 (X)	01/05/91	36.50	40.20 >
MBC: E	1-4 (X)	01/05/91	1.40	2.70
MBC: M	4-8 (X)	01/05/91	5.70	5.70
MBC: B	0-2 (X)	01/05/91	0.70	1.20
PLATELETS	150000-400000 (/MM3)	01/05/91	251000	263000
NA+	135-145 (MEQ/L)	01/05/91	140.00	139.00
K+	3.5-4.5 (MEQ/L)	01/05/91	3.50	3.90
CL-	95-105 (MEQ/L)	01/05/91	100.00	97.00
Ca++	88-104 (MG/L)	01/05/91	93.00	92.00
PO4--	25-45 (MG/L)	01/05/91	31.00	33.00
SGOT	5-35 (UI/L)	01/05/91	11.00	11.00
SGPT	5-35 (UI/L)	01/05/91	12.00	16.00
GAMMA GT	5-40 (UI/L)	01/05/91	7.00	9.00
LDH	140-330 (UI/L)	01/05/91	170.00	177.00
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	92.00	86.00
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.82	0.81
UREA	0.15-0.5 (G/L)	01/05/91	0.28	0.17
CREATININE	6-12 (MG/L)	01/05/91	9.80	9.10
URIC ACID	20-60 (MG/L)	01/05/91	51.00	53.00
TOT. BILIRUBIN	3-20 (UMOL/L)	01/05/91	5.00	3.00
TOT. PROTEINS	60-80 (G/L)	01/05/91	71.00	70.00
ALBUMINE	37-42 (G/L)	01/05/91	47.80 >	47.60 >
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	1.90	2.00
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	0.47	0.61
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	1.99	1.89
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	4.83	4.90
GLOBULINS BETA	5-8 (G/L)	01/05/91	7.24	7.00
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	9.16	8.61
TSH	0.15-3.2 (UUI/ML)	01/05/91	1.79	
T4	7-18 (PG/ML)	01/05/91	13.40	

1805

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: S12 Treatment: Placebo Sex: Female

			Visit number / Laboratory date	
			Screen	
			27/03/92	
			value	(*)
Laboratory test	Range value	Range date		
HB	11.5-15 (G/DL)	01/05/91	13.50	
HT	37-47 (X)	01/05/91	40.00	
RBC	4000000-5000000 (/MM3)	01/05/91	4940000	
WBC	5000-10000 (/MM3)	01/05/91	4460.00	<
WBC: N	50-70 (X)	01/05/91	23.20	<<
WBC: L	25-40 (X)	01/05/91	71.00	>>
WBC: E	1-4 (X)	01/05/91	2.60	
WBC: M	4-8 (X)	01/05/91	2.50	<
WBC: B	0-2 (X)	01/05/91	0.70	
PLATELETS	150000-400000 (/MM3)	01/05/91	291000	
NA+	135-145 (MEQ/L)	01/05/91	137.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	4.10	
CL-	95-105 (MEQ/L)	01/05/91	101.00	
Ca++	88-104 (MG/L)	01/05/91	93.00	
PO4--	25-45 (MG/L)	01/05/91	35.00	
SGOT	5-35 (UI/L)	01/05/91	8.00	
SGPT	5-35 (UI/L)	01/05/91	12.00	
GAMMA GT	5-40 (UI/L)	01/05/91	8.00	
LDH	140-330 (UI/L)	01/05/91	145.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	56.00	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.93	
UREA	0.15-0.5 (G/L)	01/05/91	0.29	
CREATININE	6-12 (MG/L)	01/05/91	10.50	
URIC ACID	20-60 (MG/L)	01/05/91	36.00	
TOT BILIRUBIN	3-20 (UMDL/L)	01/05/91	2.00	<
TOT. PROTEINS	60-80 (G/L)	01/05/91	75.00	
ALBUMINE	37-42 (G/L)	01/05/91	47.60	>
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	2.14	
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	1.62	>
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	3.45	>
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	5.40	
GLOBULINS BETA	5-8 (G/L)	01/05/91	7.35	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	11.30	
TSH	0.15-3.2 (UUI/ML)	01/05/91	1.01	
T4	7-18 (PG/ML)	01/05/91	14.10	

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 6/3 Patient: 513 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/05/92		02/06/92		23/06/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11.5-15 (G/DL)	01/05/91	13.40		13.50		14.50	
HT	37-47 (X)	01/05/91	38.00		40.00		42.00	
RBC	4000000-5000000 (/MM3)	01/05/91	4200000		4310000		4510000	
NBC	5000-10000 (/MM3)	01/05/91	4470.00	<	6090.00		5890.00	
NBC: N	50-70 (X)	01/05/91	76.10	>	67.90		67.80	
NBC: L	25-40 (X)	01/05/91	18.70	<	28.10		25.10	
NBC: E	1-4 (X)	01/05/91	1.70		2.00		2.40	
NBC: M	4-8 (X)	01/05/91	2.80	<	1.20	<	3.80	<
NBC: B	0-2 (X)	01/05/91	0.70		0.80		0.90	
PLATELETS	150000-400000 (/MM3)	01/05/91	333000		340000		353000	
NA+	135-145 (MEQ/L)	01/05/91	138.00		138.00		138.00	
K+	3.5-4.5 (MEQ/L)	01/05/91	3.50		3.50		3.50	
CL-	95-105 (MEQ/L)	01/05/91	101.00		100.00		97.00	
Ca++	88-104 (MG/L)	01/05/91	89.00		87.00	<	90.00	
PO4--	25-45 (MG/L)	01/05/91	27.00		27.00		31.00	
SGOT	5-35 (UI/L)	01/05/91	15.00		13.00		12.00	
SGPT	5-35 (UI/L)	01/05/91	11.00		7.00		20.00	
GAMMA GT	5-40 (UI/L)	01/05/91	12.00		12.00		14.00	
LDH	140-330 (UI/L)	01/05/91	185.00		174.00		179.00	
ALK. PHOSPH.	50-130 (UI/L)	01/05/91	44.00	<	41.00	<	55.00	
GLUCOSE	0.8-1.1 (G/L)	01/05/91	0.77	<	0.88		0.78	<
UREA	0.15-0.5 (G/L)	01/05/91	0.28		0.32		0.30	
CREATININE	6-12 (MG/L)	01/05/91	8.70		10.30		10.30	
URIC ACID	20-60 (MG/L)	01/05/91	29.00		29.00		26.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/91	4.00		4.00		4.00	
TOT. PROTEINS	60-80 (G/L)	01/05/91	71.00		71.00		76.00	
ALBUMINE	37-42 (G/L)	01/05/91	47.90	>	38.40		50.50	>
TOT. CHOLEST.	1.8-2.5 (G/L)	01/05/91	1.95		1.97		2.34	
TRIGLYCERIDES	0.25-1.6 (G/L)	01/05/91	0.90		1.50		0.93	
GLOBULINS ALPHA 1	1-3 (G/L)	01/05/91	2.27		1.85		1.98	
GLOBULINS ALPHA 2	4-7 (G/L)	01/05/91	5.40		5.96		5.32	
GLOBULINS BETA	5-8 (G/L)	01/05/91	7.03		9.37	>	7.90	
GLOBULINS GAMMA	8-12 (G/L)	01/05/91	8.45		15.40	>	10.30	
TSH	0.15-3.2 (UUI/ML)	01/05/91	0.81					
T4	7-18 (PG/ML)	01/05/91	15.60					

1807

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/02 Patient: 181 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/01/92		17/02/92		09/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	130-180 (G/L)	20/10/91	126.00	<	131.00		134.00	
HT	0.4-0.54 (L/L)	20/10/91	0.33	<<	0.37	<	0.39	<
RBC	4.2-6 (10 ¹² /L)	20/10/91	4.11	<	4.08	<	4.15	<
WBC	4.3-10 (10 ⁹ /L)	20/10/91	10.60	>	5.40		6.00	
WBC: N	25-74 (%)	20/10/91	73.00		53.00		50.00	
WBC: L	20-44 (%)	20/10/91	27.00		40.00		39.00	
WBC: E	1-5 (%)	20/10/91	0.00	<	2.00		4.00	
WBC: M	2-7 (%)	20/10/91	0.00	<	5.00		7.00	
WBC: B	0-1 (%)	20/10/91	0.00		0.00		0.00	
PLATELETS	150-440 (10 ⁹ /L)	20/10/91	334.00		219.00		243.00	
NA+	135-144 (MMOL/L)	20/10/91	138.00		139.00		136.00	
K+	3.6-5.1 (MMOL/L)	20/10/91	3.90		4.30		4.10	
CL-	97-108 (MMOL/L)	20/10/91	101.00		105.00		105.00	
Ca++	2.2-2.6 (MMOL/L)	20/10/91	2.40		2.50		2.40	
PO4--	0.84-1.45 (MMOL/L)	20/10/91	1.15		1.20		1.10	
SGOT	5-19 (U/L)	20/10/91	8.00		7.00		10.00	
SGPT	5-23 (U/L)	20/10/91	6.00		21.00		18.00	
GAMMA GT	6-28 (U/L)	20/10/91	27.00		17.00		14.00	
LDH	120-240 (U/L)	20/10/91	134.00		149.00		131.00	
ALK. PHOSPH.	40-190 (U/L)	20/10/91	218.00	>	71.00		62.00	
GLUCOSE	70-180 (MG/DL)	20/10/91	67.00	<	100.00		79.00	
BUN	10-50 (MG/DL)	20/10/91	16.00		35.00		44.00	
CREATININE	0.7-1.4 (MG/DL)	20/10/91	0.90		0.90		0.80	
URIC ACID	2-6.8 (MG/DL)	20/10/91	5.30		5.20		4.80	
TOT. BILIRUBIN	0.2-1 (MG/DL)	20/10/91	0.50		0.60		0.70	
TOT. PROTEINS	61-82 (G/L)	20/10/91	68.00		72.00		70.00	
ALBUMINE	35-55 (G/L)	20/10/91	59.40	>	57.50	>	60.50	>
TOT. CHOLEST.	130-250 (MG/DL)	20/10/91	282.00	>	177.00		189.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/10/91	157.00		83.00		64.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	20/10/91	3.90		3.00		3.10	
GLOBULINS ALPHA 2	5.9-11.1 (%)	20/10/91	12.20	>	8.60		6.60	
GLOBULINS BETA	7.9-13.9 (%)	20/10/91	10.20		12.00		12.50	
GLOBULINS GAMMA	10-18.2 (%)	20/10/91	14.30		18.90	>	17.30	
TSH	0.1-3.5 (UU/ML)	20/10/91	0.28					
T4	0.8-2 (NG/DL)	20/10/91	0.79	<				

1808

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/02 Patient: 182 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/11/91		13/12/91		03/01/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	130-180 (G/L)	20/10/91	139.00		141.00		142.00	
HT	0.4-0.54 (L/L)	20/10/91	0.41		0.40	<	0.38 <	
RBC	4.2-6 (10 ¹² /L)	20/10/91	4.33		4.44		4.46	
WBC	4.3-10 (10 ⁹ /L)	20/10/91	9.20		9.50		8.40	
WBC: N	25-74 (%)	20/10/91	70.00		64.00		50.00	
WBC: L	20-44 (%)	20/10/91	28.00		32.00		44.00	
WBC: E	1-5 (%)	20/10/91	2.00		2.00		2.00	
WBC: M	2-7 (%)	20/10/91	0.00	<	2.00		4.00	
WBC: B	0-1 (%)	20/10/91	0.00		0.00		0.00	
PLATELETS	150-440 (10 ⁹ /L)	20/10/91	401.00		397.00		372.00	
NA+	135-144 (MMOL/L)	20/10/91	145.00	>	138.00		136.00	
K+	3.6-5.1 (MMOL/L)	20/10/91	4.40		4.40		4.30	
CL-	97-108 (MMOL/L)	20/10/91	105.00		103.00		104.00	
Ca++	2.2-2.6 (MMOL/L)	20/10/91	2.60		2.40		2.40	
PO4--	0.84-1.45 (MMOL/L)	20/10/91	1.10		1.16		1.24	
SGOT	5-19 (U/L)	20/10/91	9.00		8.00		8.00	
SGPT	5-23 (U/L)	20/10/91	16.00		8.00		7.00	
GAMMA GT	6-28 (U/L)	20/10/91	12.00		12.00		12.00	
LDH	120-240 (U/L)	20/10/91	159.00		162.00		133.00	
ALK. PHOSPH.	40-190 (U/L)	20/10/91	120.00		118.00		99.00	
GLUCOSE	70-180 (MG/DL)	20/10/91	70.00		68.00	<	75.00	
BUN	10-50 (MG/DL)	20/10/91	38.00		25.00		32.00	
CREATININE	0.7-1.4 (MG/DL)	20/10/91	0.90		0.80		0.80	
URIC ACID	2-6.8 (MG/DL)	20/10/91	5.30		5.10		5.30	
TOT. BILIRUBIN	0.2-1 (MG/DL)	20/10/91	0.80		0.70		0.50	
DIR. BILIRUBIN	0-0.3 (MG/DL)	20/10/91	0.00		0.00		0.00	
TOT. PROTEINS	61-82 (G/L)	20/10/91	69.00		67.00		67.00	
ALBUMINE	35-55 (G/L)	20/10/91	57.50	>	65.70	>	65.40 >	
TOT. CHOLEST.	130-250 (MG/DL)	20/10/91	271.00	>	236.00		307.00 >	
TRIGLYCERIDES	45-200 (MG/DL)	20/10/91	124.00		79.00		201.00 >	
GLOBULINS ALPHA 1	1.6-5.8 (%)	20/10/91	4.00		2.90		3.00	
GLOBULINS ALPHA 2	5.9-11.1 (%)	20/10/91	12.00	>	9.90		10.70	
GLOBULINS BETA	7.9-13.9 (%)	20/10/91	11.70		10.90		9.70	
GLOBULINS GAMMA	10-18.2 (%)	20/10/91	14.80		10.60		13.10	
TSH	0.1-3.5 (UU/ML)	20/10/91	0.79					
T4	0.8-2 (NG/DL)	20/10/91	0.67	<<				

1809

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
.** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/02 Patient: 183 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			30/12/91		22/01/92	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	130-180 (G/L)	20/10/91	147.00		147.00	
HT	0.4-0.54 (L/L)	20/10/91	0.42		0.40	<
RBC	4.2-6 (10 ¹² /L)	20/10/91	4.82		4.93	
MBC	4.3-10 (10 ⁹ /L)	20/10/91	7.50		8.40	
MBC: N	25-74 (%)	20/10/91	60.00		64.00	
MBC: L	20-44 (%)	20/10/91	40.00		34.00	
MBC: E	1-5 (%)	20/10/91	0.00	<	0.00	<
MBC: M	2-7 (%)	20/10/91	0.00	<	2.00	
MBC: B	0-1 (%)	20/10/91	0.00		0.00	
PLATELETS	150-440 (10 ⁹ /L)	20/10/91	301.00		269.00	
NA+	135-144 (MMOL/L)	20/10/91	140.00		135.00	
K+	3.6-5.1 (MMOL/L)	20/10/91	3.90		4.60	
CL-	97-108 (MMOL/L)	20/10/91	101.00		103.00	
Ca++	2.2-2.6 (MMOL/L)	20/10/91	2.50		2.50	
PO4--	0.84-1.45 (MMOL/L)	20/10/91	0.90		1.03	
SGOT	5-19 (U/L)	20/10/91	10.00		8.00	
SGPT	5-23 (U/L)	20/10/91	18.00		14.00	
GAMMA GT	6-28 (U/L)	20/10/91	29.00	>	20.00	
LDH	120-240 (U/L)	20/10/91	143.00		121.00	
ALK. PHOSPH.	40-190 (U/L)	20/10/91	138.00		133.00	
GLUCOSE	70-180 (MG/DL)	20/10/91	84.00		91.00	
BUN	10-50 (MG/DL)	20/10/91	27.00		7.00	<
CREATININE	0.7-1.4 (MG/DL)	20/10/91	1.00		0.70	
URIC ACID	2-6.8 (MG/DL)	20/10/91	4.40		4.10	
TOT BILIRUBIN	0.2-1 (MG/DL)	20/10/91	1.00		1.00	
DIR BILIRUBIN	0-0.3 (MG/DL)	20/10/91	0.00		0.00	
TOT. PROTEINS	61-82 (G/L)	20/10/91	68.00		68.00	
ALBUMINE	35-55 (G/L)	20/10/91	71.30	>	66.20	>
TOT. CHOLEST.	130-250 (MG/DL)	20/10/91	231.00		240.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/10/91	137.00		151.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	20/10/91	2.60		2.60	
GLOBULINS ALPHA 2	5.9-11.1 (%)	20/10/91	8.30		8.60	
GLOBULINS BETA	7.9-13.9 (%)	20/10/91	8.50		11.20	
GLOBULINS GAMMA	10-18.2 (%)	20/10/91	9.30	<	11.50	
TSH	0.1-3.5 (UU/ML)	20/10/91	0.03	<<		
T4	0.8-2 (NG/DL)	20/10/91	1.63			

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(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/02 Patient: 184 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/01/92		17/02/92		09/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	120-160 (G/L)	20/10/91	138.00		126.00		135.00	
HT	0.37-0.47 (L/L)	20/10/91	0.38		0.36 <		0.39	
RBC	4-5.5 (10 ¹² /L)	20/10/91	4.23		3.92 <		4.14	
WBC	4.3-10 (10 ⁹ /L)	20/10/91	9.70		5.30		5.80	
WBC: N	25-74 (%)	20/10/91	56.00		48.00		45.00	
WBC: L	20-44 (%)	20/10/91	40.00		44.00		52.00 >	
WBC: E	1-5 (%)	20/10/91	2.00		2.00		2.00	
WBC: M	2-7 (%)	20/10/91	2.00		6.00		1.00 <	
WBC: B	0-1 (%)	20/10/91	0.00		0.00		0.00	
PLATELETS	150-440 (10 ⁹ /L)	20/10/91	532.00 >		204.00		234.00	
NA+	135-144 (MMOL/L)	20/10/91	136.00		140.00		137.00	
K+	3.6-5.1 (MMOL/L)	20/10/91	4.80		4.20		3.90	
CL-	97-108 (MMOL/L)	20/10/91	99.00		105.00		104.00	
Ca++	2.2-2.6 (MMOL/L)	20/10/91	2.40		2.50		2.40	
PO4--	0.84-1.45 (MMOL/L)	20/10/91	1.21		1.24		1.05	
SGOT	5-15 (U/L)	20/10/91	9.00		5.00		12.00	
SGPT	5-19 (U/L)	20/10/91	10.00		17.00		26.00 >	
GAMMA GT	4-18 (U/L)	20/10/91	21.00 >		14.00		18.00	
LDH	120-240 (U/L)	20/10/91	150.00		119.00 <		154.00	
ALK. PHOSPH.	40-190 (U/L)	20/10/91	103.00		59.00		81.00	
GLUCOSE	70-180 (MG/DL)	20/10/91	69.00 <		100.00		90.00	
BUN	10-50 (MG/DL)	20/10/91	34.00		34.00		42.00	
CREATININE	0.5-1.2 (MG/DL)	20/10/91	0.60		0.90		0.80	
URIC ACID	2-6.3 (MG/DL)	20/10/91	4.10		5.30		4.80	
TOT. BILIRUBIN	0.2-1 (MG/DL)	20/10/91	0.30		0.60		0.70	
TOT. PROTEINS	61-82 (G/L)	20/10/91	73.00		70.00		70.00	
ALBUMINE	35-55 (G/L)	20/10/91	53.20		58.00 >		60.60 >	
TOT. CHOLEST.	130-250 (MG/DL)	20/10/91	166.00		170.00		159.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/10/91	130.00		78.00		61.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	20/10/91	4.40		2.30		3.30	
GLOBULINS ALPHA 2	5.9-11.1 (%)	20/10/91	12.20 >		7.30		6.30	
GLOBULINS BETA	7.9-13.9 (%)	20/10/91	11.40		12.50		13.30	
GLOBULINS GAMMA	10-18.2 (%)	20/10/91	17.80		19.90 >		16.60	
TSH	0.1-3.5 (UU/ML)	20/10/91	0.73					
T4	0.8-2 (NG/DL)	20/10/91	1.18					

1811

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/02 Patient: 185 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			09/04/92		30/04/92	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	130-180 (G/L)	20/10/91	147.00		138.00	
HT	0.4-0.54 (L/L)	20/10/91	0.43		0.41	
RBC	4.2-6 (10 ¹² /L)	20/10/91	5.19		4.87	
MBC	4.3-10 (10 ⁹ /L)	20/10/91	10.40	>	7.70	
MBC: N	25-74 (%)	20/10/91	80.00	>	64.00	
MBC: L	20-44 (%)	20/10/91	16.00	<	30.00	
MBC: E	1-5 (%)	20/10/91	0.00	<	2.00	
MBC: M	2-7 (%)	20/10/91	4.00		4.00	
MBC: B	0-1 (%)	20/10/91	0.00		0.00	
PLATELETS	150-440 (10 ⁹ /L)	20/10/91	315.00		282.00	
NA+	135-144 (MMOL/L)	20/10/91	134.00	<	140.00	
K+	3.6-5.1 (MMOL/L)	20/10/91	4.20		4.50	
CL-	97-108 (MMOL/L)	20/10/91	103.00		101.00	
Ca++	2.2-2.6 (MMOL/L)	20/10/91	2.50		2.50	
PO4--	0.84-1.45 (MMOL/L)	20/10/91	1.12		1.28	
SGOT	5-19 (U/L)	20/10/91	13.00		8.00	
SGPT	5-23 (U/L)	20/10/91	17.00		18.00	
GAMMA GT	6-28 (U/L)	20/10/91	57.00	>>	112.00 >>	
LDH	120-240 (U/L)	20/10/91	139.00		112.00 <	
ALK. PHOSPH.	40-190 (U/L)	20/10/91	217.00	>	174.00	
GLUCOSE	70-180 (MG/DL)	20/10/91	145.00		258.00 >>	
BUN	10-50 (MG/DL)	20/10/91	27.00		33.00	
CREATININE	0.7-1.4 (MG/DL)	20/10/91	1.00		0.80	
URIC ACID	2-6.8 (MG/DL)	20/10/91	5.10		5.50	
TOT BILIRUBIN	0.2-1 (MG/DL)	20/10/91	0.80		0.70	
TOT. PROTEINS	61-82 (G/L)	20/10/91	77.00		72.00	
ALBUMINE	35-55 (G/L)	20/10/91	61.20	>	61.10 >	
TOT. CHOLEST.	130-250 (MG/DL)	20/10/91	223.00	>	230.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/10/91	257.00	>	180.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	20/10/91	1.30	<	2.20	
GLOBULINS ALPHA 2	5.9-11.1 (%)	20/10/91	6.90		7.60	
GLOBULINS BETA	7.9-13.9 (%)	20/10/91	12.80		10.90	
GLOBULINS GAMMA	10-18.2 (%)	20/10/91	17.80		18.20	
TSH	0.1-3.5 (UU/ML)	20/10/91	0.71			
T4	0.8-2 (NG/DL)	20/10/91	1.00			

1812

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/02 Patient: 186 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/04/92		06/05/92		27/05/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	130-180 (G/L)	20/10/91	151.00		131.00		141.00	
HT	0.4-0.54 (L/L)	20/10/91	0.44		0.40	<	0.43	
RBC	4.2-6 (10 ¹² /L)	20/10/91	4.95		4.47		4.93	
HBC	4.3-10 (10 ⁹ /L)	20/10/91	9.50		7.90		7.60	
HBC: N	25-74 (%)	20/10/91	64.00		52.00		54.00	
HBC: L	20-44 (%)	20/10/91	26.00		42.00		44.00	
HBC: E	1-5 (%)	20/10/91	0.00	<	4.00		0.00	
HBC: M	2-7 (%)	20/10/91	10.00	>>	2.00		2.00	
HBC: B	0-1 (%)	20/10/91	0.00		0.00		0.00	
PLATELETS	150-440 (10 ⁹ /L)	20/10/91	337.00		292.00		540.00	
NA+	135-144 (MMOL/L)	20/10/91	142.00		134.00	<	139.00	
K+	3.6-5.1 (MMOL/L)	20/10/91	4.20		3.80		4.30	
CL-	97-108 (MMOL/L)	20/10/91	101.00		104.00		102.00	
Ca++	2.2-2.6 (MMOL/L)	20/10/91	2.60		2.30		2.50	
PO4--	0.84-1.45 (MMOL/L)	20/10/91	0.82	<	1.09		1.16	
SGOT	5-19 (U/L)	20/10/91	11.00		12.00		10.00	
SGPT	5-23 (U/L)	20/10/91	17.00		7.00		16.00	
GAMMA GT	6-28 (U/L)	20/10/91	13.00		8.00		16.00	
LDH	120-240 (U/L)	20/10/91	147.00		90.00	<	138.00	
ALK. PHOSPH.	40-190 (U/L)	20/10/91	100.00		89.00		119.00	
GLUCOSE	70-180 (MG/DL)	20/10/91	59.00	<	70.00		80.00	
BUN	10-50 (MG/DL)	20/10/91	26.00		26.00		18.00	
CREATININE	0.7-1.4 (MG/DL)	20/10/91	0.80		0.70		0.80	
URIC ACID	2-6.8 (MG/DL)	20/10/91	6.60		4.50		5.20	
TOT. BILIRUBIN	0.2-1 (MG/DL)	20/10/91	0.60		0.50		0.70	
TOT. PROTEINS	61-82 (G/L)	20/10/91	79.00		67.00		70.00	
ALBUMINE	35-55 (G/L)	20/10/91	69.10	>	66.00	>	61.70	
TOT. CHOLEST.	130-250 (MG/DL)	20/10/91	191.00		181.00		167.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/10/91	157.00		84.00		51.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	20/10/91	2.20		2.60		3.70	
GLOBULINS ALPHA 2	5.9-11.1 (%)	20/10/91	7.20		8.10		10.50	
GLOBULINS BETA	7.9-13.9 (%)	20/10/91	9.70		9.90		9.90	
GLOBULINS GAMMA	10-18.2 (%)	20/10/91	11.80		13.40		14.20	
TSH	0.1-3.5 (UU/ML)	20/10/91	0.65					
T4	0.8-2 (NG/DL)	20/10/91	1.36					

1813

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/02 Patient: 535 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/04/92		09/05/92		27/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	130-180 (G/L)	20/10/91	153.00		135.00		147.00	
HT	0.4-0.54 (L/L)	20/10/91	0.44		0.39 <		0.43	
RBC	4.2-6 (10 ¹² /L)	20/10/91	4.95		4.12 <		4.94	
WBC	4.3-10 (10 ⁹ /L)	20/10/91	6.80		6.10		7.70	
WBC: N	25-74 (%)	20/10/91	57.00		47.00		33.00	
WBC: L	20-44 (%)	20/10/91	34.00		44.00		64.00 >>	
WBC: E	1-5 (%)	20/10/91	1.00		2.00		2.00	
WBC: M	2-7 (%)	20/10/91	8.00	>	7.00		0.00 <	
WBC: B	0-1 (%)	20/10/91	1.00		0.00		1.00	
PLATELETS	150-440 (10 ⁹ /L)	20/10/91	256.00		253.00		345.00	
NA+	135-144 (MMOL/L)	20/10/91	139.00		137.00		137.00	
K+	3.6-5.1 (MMOL/L)	20/10/91	4.30		4.00		4.40	
CL-	97-108 (MMOL/L)	20/10/91	108.00		103.00		101.00	
Ca++	2.2-2.6 (MMOL/L)	20/10/91	2.40		2.40		2.50	
PO4--	0.84-1.45 (MMOL/L)	20/10/91	1.21		1.12		1.22	
SGOT	5-19 (U/L)	20/10/91	11.00		12.00		17.00	
SGPT	5-23 (U/L)	20/10/91	13.00		18.00		9.00	
GAMMA GT	6-28 (U/L)	20/10/91	22.00		14.00		10.00	
LDH	120-240 (U/L)	20/10/91	147.00		117.00 <		190.00	
ALK. PHOSPH.	40-190 (U/L)	20/10/91	107.00		51.00		57.00	
GLUCOSE	70-180 (MG/DL)	20/10/91	76.00		94.00		79.00	
BUN	10-50 (MG/DL)	20/10/91	38.00		46.00		30.00	
CREATININE	0.7-1.4 (MG/DL)	20/10/91	1.10		1.00		0.90	
URIC ACID	2-6.8 (MG/DL)	20/10/91	6.80		5.20		5.90	
TOT. BILIRUBIN	0.2-1 (MG/DL)	20/10/91	0.80		1.00		0.70	
TOT. PROTEINS	61-82 (G/L)	20/10/91	73.00		73.00		73.00	
ALBUMINE	35-55 (G/L)	20/10/91	70.90	>	64.20 >		80.00 >>	
TOT. CHOLEST.	130-250 (MG/DL)	20/10/91	224.00		193.00		165.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/10/91	136.00		99.00		90.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	20/10/91	1.60		1.80		3.20	
GLOBULINS ALPHA 2	5.9-11.1 (%)	20/10/91	7.80		5.90		7.80	
GLOBULINS BETA	7.9-13.9 (%)	20/10/91	9.40		10.10		9.80	
GLOBULINS GAMMA	10-18.2 (%)	20/10/91	10.30		18.00		17.20	
TSH	0.1-3.5 (UU/ML)	20/10/91	1.97					
T4	0.8-2 (NG/DL)	20/10/91	1.01					

1814

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/02 Patient: 536 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/05/92		29/05/92		22/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	120-160 (G/L)	20/10/91	131.00		126.00		128.00	
HT	0.37-0.47 (L/L)	20/10/91	0.39		0.36 <		0.38	
RBC	4-5.5 (10 ¹² /L)	20/10/91	4.59		3.93 <		4.07	
MBC	4.3-10 (10 ⁹ /L)	20/10/91	4.80		6.50		6.20	
MBC: N	25-74 (%)	20/10/91	56.00		56.00		54.00	
MBC: L	20-44 (%)	20/10/91	36.00		44.00		37.00	
MBC: E	1-5 (%)	20/10/91	2.00				7.00 >>	
MBC: M	2-7 (%)	20/10/91	6.00				1.00 <	
MBC: B	0-1 (%)	20/10/91	0.00				1.00	
PLATELETS	150-440 (10 ⁹ /L)	20/10/91	402.00		204.00		203.00	
NA+	135-144 (MMOL/L)	20/10/91	134.00 <		135.00		140.00	
K+	3.6-5.1 (MMOL/L)	20/10/91	3.80		4.30		4.50	
CL-	97-108 (MMOL/L)	20/10/91	102.00		101.00		105.00	
Ca++	2.2-2.6 (MMOL/L)	20/10/91	2.30		2.40		2.60	
PO4--	0.84-1.45 (MMOL/L)	20/10/91	1.23		1.11		1.37	
SGOT	5-15 (U/L)	20/10/91	12.00		7.00		8.00	
SGPT	5-19 (U/L)	20/10/91	4.00 <		6.00		7.00	
GAMMA GT	4-18 (U/L)	20/10/91	18.00		8.00		9.00	
LDH	120-240 (U/L)	20/10/91	213.00		130.00		128.00	
ALK. PHOSPH.	40-190 (U/L)	20/10/91	111.00		88.00		75.00	
GLUCOSE	70-180 (MG/DL)	20/10/91	60.00 <		79.00		72.00	
BUN	10-50 (MG/DL)	20/10/91	26.00		27.00		27.00	
CREATININE	0.5-1.2 (MG/DL)	20/10/91	0.70		0.60		0.70	
URIC ACID	2-6.3 (MG/DL)	20/10/91			3.50		3.70	
TOT. BILIRUBIN	0.2-1 (MG/DL)	20/10/91	0.60		0.60		1.00	
TOT. PROTEINS	61-82 (G/L)	20/10/91	63.00		65.00		65.00	
ALBUMINE	35-55 (G/L)	20/10/91	65.00 >		63.40 >		65.50 >	
TOT. CHOLEST.	130-250 (MG/DL)	20/10/91	262.00 >		194.00		196.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/10/91	75.00		101.00		117.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	20/10/91	2.80		2.30		2.30	
GLOBULINS ALPHA 2	5.9-11.1 (%)	20/10/91	9.80		8.70		9.20	
GLOBULINS BETA	7.9-13.9 (%)	20/10/91	11.10		9.90		8.60	
GLOBULINS GAMMA	10-18.2 (%)	20/10/91	11.30		15.80		14.40	
TSH	0.1-3.5 (UU/ML)	20/10/91	1.59					
T4	0.8-2 (NG/DL)	20/10/91	1.22					

1815

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 187 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/02/92		10/03/92		31/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/02/92	13.70		14.10		14.10	
HT	37-54 (%)	01/02/92	43.30		46.70		44.00	
RBC	3.8-5.2 (10 ⁶ /UL)	01/02/92	4.76		4.99		4.81	
WBC	4-10.8 (10 ³ /UL)	01/02/92	6.87		7.18		6.96	
WBC: N	45-70 (%)	01/02/92	39.00	<	58.00		53.50	
WBC: L	25-45 (%)	01/02/92	52.10	>	34.20		35.20	
WBC: E	1-5 (%)	01/02/92	1.40		1.00		1.80	
WBC: M	1-9 (%)	01/02/92	4.80		3.80		4.30	
WBC: B	0-2 (%)	01/02/92	0.60		0.60		2.20 >	
PLATELETS	150-450 (10 ³ /UL)	01/02/92	242.00		266.00		301.00	
NA+	132-151 (MMOL/L)	01/02/92	140.00		144.00		146.00	
K+	3.6-5.2 (MMOL/L)	01/02/92	4.89		5.30 >		6.76 >>	
CL-	97-108 (MMOL/L)	01/02/92	98.00		100.00		97.00	
Ca++	2.2-2.65 (MMOL/L)	01/02/92	2.37		2.63		2.43	
PO4--	2.5-5 (MG/DL)	01/02/92	4.30		7.80 >>		5.30 >	
SGOT	5-15 (U/L)	01/02/92	8.00		12.00		13.00	
SGPT	5-19 (U/L)	01/02/92	9.00		15.00		12.00	
GAMMA GT	5-18 (U/L)	01/02/92	14.00		18.00		19.00 >	
LDH	150-240 (U/L)	01/02/92	219.00		225.00		355.00 >	
ALK. PHOSPH.	65-175 (U/L)	01/02/92	122.00		138.00		129.00	
GLUCOSE	50-100 (MG/DL)	01/02/92	91.00		94.00		106.00 >	
BUN	10-50 (MG/DL)	01/02/92	27.30		21.70		27.90	
CREATININE	0.5-0.9 (MG/DL)	01/02/92	0.98 >		1.36 >>		1.07 >	
URIC ACID	2.5-6 (MG/DL)	01/02/92	5.30		5.90		6.20 >	
TOT. BILIRUBIN	0.2-1 (MG/DL)	01/02/92	0.40		0.43		0.28	
TOT. PROTEINS	6-8.5 (G/DL)	01/02/92	7.00		7.70		8.00	
ALBUMINE	55-68 (%)	01/02/92	61.70		65.50		61.70	
TOT. CHOLEST.	120-220 (MG/DL)	01/02/92	338.00 >>		348.00 >>		370.00 >>	
TRIGLYCERIDES	45-200 (MG/DL)	01/02/92	182.00		232.00 >		237.00 >	
GLOBULINS ALPHA 1	1-5 (%)	01/02/92	3.20		2.20		2.50	
GLOBULINS ALPHA 2	5-10 (%)	01/02/92	8.90		7.70		11.30 >	
GLOBULINS BETA	7-12 (%)	01/02/92	9.40		8.60		8.30	
GLOBULINS GAMMA	11-20 (%)	01/02/92	16.80		16.00		16.20	
TSH	0.3-3 (MU/L)	01/02/92	4.90	>>				
T4	4.5-12 (NG/DL)	01/02/92	6.00					

1816

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 188 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/02/92		17/03/92		07/04/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	10/02/92	15.50		16.30		15.90	
HT	40-54 (%)	10/02/92	49.60		55.80	>	51.70	
RBC	4.4-5.9 (10 ⁶ /UL)	10/02/92	5.24		5.41		5.10	
WBC	4-10.8 (10 ³ /UL)	10/02/92	9.80		12.51	>	13.17	
WBC: N	45-70 (%)	10/02/92	63.40		78.00	>	75.10	
WBC: L	25-45 (%)	10/02/92	20.20	<	12.60	<<	14.60	
WBC: E	1-5 (%)	10/02/92	5.20	>	1.70		2.10	
WBC: M	1-9 (%)	10/02/92	7.80		5.50		5.60	
WBC: B	0-2 (%)	10/02/92	1.10		0.70		0.80	
PLATELETS	150-450 (10 ³ /UL)	10/02/92	209.00		198.00		186.00	
NA+	132-151 (MMOL/L)	10/02/92	138.00		142.00		142.00	
K+	3.6-5.2 (MMOL/L)	10/02/92	8.46	>>			6.13	
CL-	97-108 (MMOL/L)	10/02/92	93.00	<	104.00		102.00	
Ca ⁺⁺	2.2-2.65 (MMOL/L)	10/02/92	2.54		2.60		2.52	
PO4--	2.5-5 (MG/DL)	10/02/92	3.20		9.60	>>	7.12	
SGOT	5-19 (U/L)	10/02/92	8.00		5.00		9.00	
SGPT	5-23 (U/L)	10/02/92	10.00		12.00		11.00	
GAMMA GT	5-28 (U/L)	10/02/92	18.00		16.00		15.00	
LDH	150-240 (U/L)	10/02/92	191.00		340.00	>	185.00	
ALK. PHOSPH.	65-175 (U/L)	10/02/92	121.00		105.00		122.00	
GLUCOSE	50-100 (MG/DL)	10/02/92	84.00		103.00	>	93.00	
BUN	10-50 (MG/DL)	10/02/92	17.60		25.80		23.20	
CREATININE	0.6-1.1 (MG/DL)	10/02/92	0.74		1.28	>	1.15	
URIC ACID	3.5-7 (MG/DL)	10/02/92	4.00		3.70		3.90	
TOT BILIRUBIN	0.2-1 (MG/DL)	10/02/92	0.46		0.32		0.34	
TOT. PROTEINS	6-8.5 (G/DL)	10/02/92	7.30		8.00		7.30	
ALBUMINE	55-68 (%)	10/02/92	75.10	>	69.70	>	68.20	
TOT. CHOLEST.	120-220 (MG/DL)	10/02/92	192.00		217.00		192.00	
TRIGLYCERIDES	45-200 (MG/DL)	10/02/92	299.00	>>	222.00	>	270.00	
GLOBULINS ALPHA 1	1-5 (%)	10/02/92	2.40		3.30		3.40	
GLOBULINS ALPHA 2	5-10 (%)	10/02/92	7.80		10.10	>	9.90	
GLOBULINS BETA	7-12 (%)	10/02/92	6.50	<	7.60		8.50	
GLOBULINS GAMMA	11-20 (%)	10/02/92	8.20	<	9.30	<	10.00	
TSH	0.3-3 (MU/L)	10/02/92	1.30					
T4	4.5-12 (NG/DL)	10/02/92	7.20					

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1817

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 189 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/02/92		17/03/92		07/04/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	05/02/92	16.30		15.10		15.00	
HT	40-54 (X)	05/02/92	52.50		48.10		47.30	
RBC	4.4-5.9 (10 ⁶ /UL)	05/02/92	5.83		5.35		5.02	
WBC	4-10.8 (10 ³ /UL)	05/02/92	8.72		8.34		13.85 >	
WBC: N	45-70 (X)	05/02/92	59.20		55.50		72.80 >	
WBC: L	25-45 (X)	05/02/92	26.10		33.40		20.80 <	
WBC: E	1-5 (X)	05/02/92	3.20		1.50		0.40 <	
WBC: M	1-9 (X)	05/02/92	6.50		5.10		3.90	
WBC: B	0-2 (X)	05/02/92	1.20		1.10		0.50	
PLATELETS	150-450 (10 ³ /UL)	05/02/92	313.00		322.00		313.00	
NA+	132-151 (MMOL/L)	05/02/92	140.00		138.00		141.00	
K+	3.6-5.2 (MMOL/L)	05/02/92			7.38 >>		6.72 >>	
CL-	97-108 (MMOL/L)	05/02/92	94.00 <		96.00 <		100.00 >	
Ca ⁺⁺	2.2-2.65 (MMOL/L)	05/02/92	2.53		2.49		2.52	
PO4 ⁻⁻⁻	2.5-5 (MG/DL)	05/02/92	2.94		4.80		5.34 >	
SGOT	5-19 (U/L)	05/02/92	11.00		10.00		9.00	
SGPT	5-23 (U/L)	05/02/92	18.00		17.00		17.00	
GAMMA GT	5-28 (U/L)	05/02/92	19.00		20.00		22.00 >	
LDH	150-240 (U/L)	05/02/92	264.00 >		243.00 >		242.00 >	
ALK. PHOSPH.	65-175 (U/L)	05/02/92	68.00		55.00 <		59.00 <	
GLUCOSE	50-100 (MG/DL)	05/02/92	97.00		100.00		108.00 >	
BUN	10-50 (MG/DL)	05/02/92	34.90		35.30		40.10	
CREATININE	0.6-1.1 (MG/DL)	05/02/92	0.85		0.96		1.12 >	
URIC ACID	3.5-7 (MG/DL)	05/02/92	6.10		5.10		5.10	
TOT. BILIRUBIN	0.2-1 (MG/DL)	05/02/92	0.67		0.38		0.37	
TOT. PROTEINS	6-8.5 (G/DL)	05/02/92	7.20		7.20		6.90	
ALBUMINE	55-68 (X)	05/02/92	66.70		67.00		66.60	
TOT. CHOLEST.	120-220 (MG/DL)	05/02/92	305.00 >>		285.00 >		266.00 >	
TRIGLYCERIDES	45-200 (MG/DL)	05/02/92	200.00		188.00		163.00	
GLOBULINS ALPHA 1	1-5 (X)	05/02/92	2.60		2.40		2.60	
GLOBULINS ALPHA 2	5-10 (X)	05/02/92	9.00		7.90		8.60	
GLOBULINS BETA	7-12 (X)	05/02/92	10.10		10.50		11.10	
GLOBULINS GAMMA	11-20 (X)	05/02/92	11.60		12.20		11.10	
TSH	0.3-3 (MU/L)	05/02/92	1.50					
T4	4.5-12 (NG/DL)	05/02/92	6.60					

1818

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value and laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 190 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/02/92		20/03/92		10/04/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	15/02/92	14.70		15.00		15.00	
HT	40-54 (%)	15/02/92	50.80		51.70		49.70	
RBC	4.4-5.9 (10 ⁶ /UL)	15/02/92	5.16		5.34		5.12	
HBC	4-10.8 (10 ³ /UL)	15/02/92	8.96		7.49		8.18	
HBC: N	45-70 (%)	15/02/92	69.50		60.50		73.20 >	
HBC: L	25-45 (%)	15/02/92	20.50	<	25.80		17.40 <<	
HBC: E	1-5 (%)	15/02/92	1.10		2.70		2.40	
HBC: H	1-9 (%)	15/02/92	5.90		7.20		4.90	
HBC: B	0-2 (%)	15/02/92	0.80		1.50		0.90	
PLATELETS	150-450 (10 ³ /UL)	15/02/92	360.00		370.00		337.00	
NA+	132-151 (MMOL/L)	15/02/92	142.00		140.00		144.00	
K+	3.6-5.2 (MMOL/L)	15/02/92	4.29				7.95 >>	
CL-	97-108 (MMOL/L)	15/02/92	96.00	<	98.00		100.00	
Ca++	2.2-2.65 (MMOL/L)	15/02/92	2.43		2.57		2.20	
PO4--	2.5-5 (MG/DL)	15/02/92	3.76		6.10	>>	17.00 >>	
SGOT	5-19 (U/L)	15/02/92	11.00		8.00		14.00	
SGPT	5-23 (U/L)	15/02/92	9.00		7.00		10.00	
GAMMA GT	5-28 (U/L)	15/02/92	11.00		12.00		12.00	
LDH	150-240 (U/L)	15/02/92	290.00	>	227.00		408.00 >	
ALK. PHOSPH.	65-175 (U/L)	15/02/92	201.00	>	207.00	>	199.00 >	
GLUCOSE	50-100 (MG/DL)	15/02/92	108.00	>	97.00		101.00 >	
BUN	10-50 (MG/DL)	15/02/92	15.50		15.30		18.30	
CREATININE	0.6-1.1 (MG/DL)	15/02/92	0.84		1.12	>	1.37 >	
URIC ACID	3.5-7 (MG/DL)	15/02/92	6.20		5.30		5.70	
TOT BILIRUBIN	0.2-1 (NG/DL)	15/02/92	0.41		0.33		0.49	
TOT. PROTEINS	6-8.5 (G/DL)	15/02/92	7.40		7.40		7.80	
ALBUMINE	55-68 (%)	15/02/92	66.00		66.20		68.50 >	
TOT. CHOLEST.	120-220 (MG/DL)	15/02/92	274.00	>	281.00	>	284.00 >	
TRIGLYCERIDES	45-200 (MG/DL)	15/02/92	167.00		136.00		112.00	
GLOBULINS ALPHA 1	1-5 (%)	15/02/92	2.80		2.50		2.60	
GLOBULINS ALPHA 2	5-10 (%)	15/02/92	8.90		10.10	>	11.00 >	
GLOBULINS BETA	7-12 (%)	15/02/92	10.20		8.50		7.30	
GLOBULINS GAMMA	11-20 (%)	15/02/92	12.10		12.70		10.60 <	
TSH	0.3-3 (MU/L)	15/02/92	2.20					
T4	4.5-12 (NG/DL)	15/02/92	7.20					

1819

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 191 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			25/02/92		24/03/92	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	20/02/92	13.80		14.20	
HT	37-54 (X)	20/02/92	45.70		44.80	
RBC	3.8-5.2 (10 ⁶ /UL)	20/02/92	4.85		4.85	
WBC	4-10.8 (10 ³ /UL)	20/02/92	6.44		8.21	
WBC: N	45-70 (X)	20/02/92	66.70		73.20 >	
WBC: L	25-45 (X)	20/02/92	23.40 <		18.20 <	
WBC: E	1-5 (X)	20/02/92	0.80 <		0.80 <	
WBC: M	1-9 (X)	20/02/92	5.10		4.90	
WBC: B	0-2 (X)	20/02/92	0.90		0.70	
PLATELETS	150-450 (10 ³ /UL)	20/02/92	274.00		323.00	
NA+	132-151 (MMOL/L)	20/02/92	144.00		140.00	
K+	3.6-5.2 (MMOL/L)	20/02/92	5.28 >		5.04	
CL-	97-108 (MMOL/L)	20/02/92	102.00		97.00	
Ca++	2.2-2.65 (MMOL/L)	20/02/92	2.38		2.35	
PO4--	2.5-5 (MG/DL)	20/02/92	3.91			
SGOT	5-15 (U/L)	20/02/92	6.00		9.00	
SGPT	5-19 (U/L)	20/02/92	7.00		10.00	
GAMMA GT	5-18 (U/L)	20/02/92	12.00		15.00	
LDH	150-240 (U/L)	20/02/92	291.00 >		260.00 >	
ALK. PHOSPH.	65-175 (U/L)	20/02/92	84.00		79.00	
GLUCOSE	50-100 (MG/DL)	20/02/92	107.00 >		110.00 >	
BUN	10-50 (MG/DL)	20/02/92	24.30		24.60	
CREATININE	0.5-0.9 (MG/DL)	20/02/92	0.68		0.63	
URIC ACID	2.5-6 (MG/DL)	20/02/92	4.20		4.40	
TOT BILIRUBIN	0.2-1 (MG/DL)	20/02/92	0.40		0.28	
TOT. PROTEINS	6-8.5 (G/DL)	20/02/92	6.90		7.00	
ALBUMINE	55-68 (X)	20/02/92	63.80		64.40	
TOT. CHOLEST.	120-220 (MG/DL)	20/02/92	201.00		216.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/02/92	98.00		123.00	
GLOBULINS ALPHA 1	1-5 (X)	20/02/92	2.80		3.00	
GLOBULINS ALPHA 2	5-10 (X)	20/02/92	7.70		8.50	
GLOBULINS BETA	7-12 (X)	20/02/92	9.00		9.00	
GLOBULINS GAMMA	11-20 (X)	20/02/92	16.70		15.10	
TSH	0.3-3 (MU/L)	20/02/92	1.00			
T4	4.5-12 (NG/DL)	20/02/92	7.80			

1820

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 192 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/03/92		31/03/92		21/04/92	
			value	(♠)	value	(♠)	value	(♠)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/92	14.50		14.50		14.40	
HT	37-54 (X)	01/03/92	48.60		47.60		48.00	
RBC	3.8-5.2 (10 ⁶ /UL)	01/03/92	5.00		4.91		4.73	
MBC	4-10.8 (10 ³ /UL)	01/03/92	7.82		5.84		5.73	
MBC: N	45-70 (X)	01/03/92	64.90		49.60		48.70	
MBC: L	25-45 (X)	01/03/92	26.10		37.20		41.20	
MBC: E	1-5 (X)	01/03/92	0.70	<	1.60		1.30	
MBC: M	1-9 (X)	01/03/92	5.40		5.80		5.40	
MBC: B	0-2 (X)	01/03/92	0.60		2.00		0.60	
PLATELETS	150-450 (10 ³ /UL)	01/03/92	265.00		257.00		280.00	
NA+	132-151 (MMOL/L)	01/03/92	146.00		143.00		145.00	
K+	3.6-5.2 (MMOL/L)	01/03/92	5.93	>	6.80	>>	5.36	
CL-	97-108 (MMOL/L)	01/03/92	100.00		98.00		104.00	
Ca++	2.2-2.65 (MMOL/L)	01/03/92	2.61		2.55		2.53	
PO4--	2.5-5 (MG/DL)	01/03/92	6.96	>>	6.20	>>	5.80	
SGOT	5-15 (U/L)	01/03/92	11.00		13.00		10.00	
SGPT	5-19 (U/L)	01/03/92	10.00		9.00		11.00	
GAMMA GT	5-18 (U/L)	01/03/92	10.00		8.00		10.00	
LDH	150-240 (U/L)	01/03/92	285.00	>	326.00	>	341.00	
ALK. PHOSPH.	65-175 (U/L)	01/03/92	149.00		140.00		139.00	
GLUCOSE	50-100 (MG/DL)	01/03/92	71.00		88.00		112.00	
BUN	10-50 (MG/DL)	01/03/92	38.20		38.70		34.40	
CREATININE	0.5-0.9 (MG/DL)	01/03/92	1.14	>	1.04	>	1.07	
URIC ACID	2.5-6 (MG/DL)	01/03/92	5.40		5.50		5.20	
TOT BILIRUBIN	0.2-1 (MG/DL)	01/03/92	0.67		0.54		0.51	
TOT. PROTEINS	6-8.5 (G/DL)	01/03/92	7.60		7.80		7.90	
ALBUMINE	55-68 (X)	01/03/92	64.40		67.00		65.70	
TOT. CHOLEST.	120-220 (MG/DL)	01/03/92	298.00	>>	281.00	>	297.00	
TRIGLYCERIDES	45-200 (MG/DL)	01/03/92	89.00		73.00		89.00	
GLOBULINS ALPHA 1	1-5 (X)	01/03/92	1.60		2.00		2.10	
GLOBULINS ALPHA 2	5-10 (X)	01/03/92	8.10		9.10		6.90	
GLOBULINS BETA	7-12 (X)	01/03/92	12.00		10.50		9.90	
GLOBULINS GAMMA	11-20 (X)	01/03/92	13.90		11.40		11.10	
TSH	0.3-3 (MU/L)	01/03/92	1.40					
T4	4.5-12 (NG/DL)	01/03/92	8.30					

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1821

(♠) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 523 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/05/92		26/05/92		16/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/92	13.50		14.90		14.30	
HT	35-47 (%)	01/04/92	40.00		48.00	>	43.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	01/04/92	4.30		4.70		4.50	
WBC	4-10 (10 ³ /MM ³)	01/04/92	4.70		5.10		5.20	
WBC: N	45-70 (%)	01/04/92	54.00		59.00		60.00	
WBC: L	25-40 (%)	01/04/92	33.00		31.00		32.00	
WBC: E	1-4 (%)	01/04/92	2.00		3.00		2.00	
WBC: M	1-8 (%)	01/04/92	7.00		3.00		4.00	
WBC: B	0-2 (%)	01/04/92	1.00		2.00		1.00	
PLATELETS	200-300 (10 ³ /MM ³)	01/04/92	235.00		287.00		281.00	
NA+	135-144 (MMOL/L)	01/04/92	147.00	>	143.00		143.00	
K+	3.6-5.6 (MMOL/L)	01/04/92	4.30		4.40		4.30	
CL-	97-108 (MMOL/L)	01/04/92	109.00	>	106.00		104.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/92	2.49		2.44		2.25	
PO4--	0.81-1.45 (MMOL/L)	01/04/92	1.32		1.14		1.13	
SGOT	5-15 (U/L)	01/04/92	8.00		6.00		7.00	
SGPT	5-17 (U/L)	01/04/92	8.00		5.00		8.00	
GAMMA GT	5-18 (U/L)	01/04/92	7.00		5.00		7.00	
LDH	150-240 (U/L)	01/04/92	149.00	<	142.00	<	151.00	
ALK. PHOSPH.	60-200 (U/L)	01/04/92	107.00		117.00		91.00	
GLUCOSE	60-110 (MG/DL)	01/04/92	91.00		88.00		102.00	
BUN	10-50 (MG/DL)	01/04/92	37.00		41.00		36.00	
CREATININE	0.5-1.2 (MG/DL)	01/04/92	0.87		0.88		0.85	
URIC ACID	2.5-6 (MG/DL)	01/04/92	2.60		1.90	<	2.20	
TOT BILIRUBIN	0.2-1 (MG/DL)	01/04/92	0.28		0.22		0.38	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/04/92	0.11					
TOT. PROTEINS	6-8 (G/DL)	01/04/92			7.20		6.70	
ALBUMINE	58.8-69.6 (%)	01/04/92	67.20		66.70		69.60	
TOT. CHOLEST.	120-220 (MG/DL)	01/04/92	210.00		194.00		182.00	
TRIGLYCERIDES	50-172 (MG/DL)	01/04/92	41.00	<	82.00		74.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/04/92	2.80		3.60		3.50	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/04/92	7.60		8.00		7.20	
GLOBULINS BETA	8.9-13.6 (%)	01/04/92	10.80		11.00		10.50	
GLOBULINS GAMMA	8.4-18.3 (%)	01/04/92	11.70		10.70		9.30	
TSH	0.2-5 (UU/ML)	01/04/92	1.30					
T4	4-13 (UG/DL)	01/04/92	6.40					

1822

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 524 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/05/92		26/05/92		16/06/92	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/92	13.40		13.60		13.70	
HT	35-47 (%)	01/04/92	38.00		39.00		38.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	01/04/92	4.40		4.50		4.50	
WBC	4-10 (10 ³ /MM ³)	01/04/92	5.30		5.00		3.80 <	
WBC: N	45-70 (%)	01/04/92	52.00		55.00		45.00	
WBC: L	25-40 (%)	01/04/92	33.00		28.00		37.00	
WBC: E	1-4 (%)	01/04/92	3.00		4.00		4.00	
WBC: M	1-8 (%)	01/04/92	9.00 >		10.00 >		12.00 >>	
WBC: B	0-2 (%)	01/04/92	1.00		1.00		1.00	
PLATELETS	200-300 (10 ³ /MM ³)	01/04/92	101.00 <<		104.00 <<		107.00 <<	
NA+	135-144 (MMOL/L)	01/04/92	149.00 >		135.00		137.00	
K+	3.6-5.6 (MMOL/L)	01/04/92	4.10		3.60		3.80	
CL-	97-108 (MMOL/L)	01/04/92	110.00 >		99.00		101.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/92	2.43		2.42		2.39	
PO4--	0.81-1.45 (MMOL/L)	01/04/92	1.04		0.96		1.11	
SGOT	5-15 (U/L)	01/04/92	8.00		6.00		7.00	
SGPT	5-17 (U/L)	01/04/92	6.00		6.00		8.00	
GAMMA GT	5-18 (U/L)	01/04/92	9.00		7.00		9.00	
LDH	150-240 (U/L)	01/04/92	146.00 <		130.00 <		114.00 <	
ALK. PHOSPH.	60-200 (U/L)	01/04/92	57.00 <		60.00		69.00	
GLUCOSE	60-110 (MG/DL)	01/04/92	54.00 <		63.00		54.00 <	
BUN	10-50 (MG/DL)	01/04/92	36.00 >		17.00		53.00 >	
CREATININE	0.5-1.2 (MG/DL)	01/04/92	0.94		0.79		0.84	
URIC ACID	2.5-6 (MG/DL)	01/04/92	4.90		3.60		3.90	
TOT. BILIRUBIN	0.2-1 (MG/DL)	01/04/92	0.35		0.38		0.32	
DIR. BILIRUBIN	0-0.25 (MG/DL)	01/04/92	0.21					
TOT. PROTEINS	6-8 (G/DL)	01/04/92	7.60		7.00		6.80	
ALBUMINE	58.8-69.6 (%)	01/04/92	63.10		66.80		69.20	
TOT. CHOLEST.	120-220 (MG/DL)	01/04/92	179.00		176.00		174.00	
TRIGLYCERIDES	50-172 (MG/DL)	01/04/92	102.00		149.00		113.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/04/92	3.60		3.70		3.50	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/04/92	11.70		8.40		7.70	
GLOBULINS BETA	8.9-13.6 (%)	01/04/92	13.00		10.40		9.50	
GLOBULINS GAMMA	8.4-18.3 (%)	01/04/92	8.60		10.70		10.10	
TSH	0.2-5 (UU/ML)	01/04/92	1.30					
T4	4-13 (UG/DL)	01/04/92	10.40					

1823

(ø) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 525 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/05/92		26/05/92		16/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/92	14.30		13.70		14.00	
HT	35-47 (X)	01/04/92	44.00		41.00		40.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	01/04/92	4.60		4.30		4.50	
WBC	4-10 (10 ³ /MM ³)	01/04/92	4.10		6.00		4.30	
WBC: N	45-70 (X)	01/04/92	56.00		53.00		49.00	
WBC: L	25-40 (X)	01/04/92	33.00		37.00		40.00	
WBC: E	1-4 (X)	01/04/92	4.00		2.00		3.00	
WBC: M	1-8 (X)	01/04/92	5.00		6.00		6.00	
WBC: B	0-2 (X)	01/04/92	1.00		1.00		1.00	
PLATELETS	200-300 (10 ³ /MM ³)	01/04/92	282.00		284.00		197.00 <	
NA+	135-144 (MMOL/L)	01/04/92	149.00 >		137.00		136.00	
K+	3.6-5.6 (MMOL/L)	01/04/92	4.40		4.80		4.30	
CL-	97-108 (MMOL/L)	01/04/92	113.00 >		105.00		101.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/92	2.47		2.26		2.27	
PO4--	0.81-1.45 (MMOL/L)	01/04/92	1.59 >		0.94		0.98	
SGOT	5-15 (U/L)	01/04/92	14.00		6.00		6.00	
SGPT	5-17 (U/L)	01/04/92	22.00 >		6.00		8.00	
GAMMA GT	5-18 (U/L)	01/04/92	35.00 >		7.00		9.00	
LDH	150-240 (U/L)	01/04/92	218.00		185.00		209.00	
ALK. PHOSPH.	60-200 (U/L)	01/04/92	135.00		85.00		86.00	
GLUCOSE	60-110 (MG/DL)	01/04/92	64.00		68.00		65.00	
BUN	10-50 (MG/DL)	01/04/92	25.00		32.00		39.00	
CREATININE	0.5-1.2 (MG/DL)	01/04/92	1.09		0.86		0.80	
URIC ACID	2.5-6 (MG/DL)	01/04/92	5.10		3.70		4.00	
TOT. BILIRUBIN	0.2-1 (MG/DL)	01/04/92	0.33		0.28		0.39	
DIR. BILIRUBIN	0-0.25 (MG/DL)	01/04/92	0.12					
TOT. PROTEINS	6-8 (G/DL)	01/04/92	6.90		6.60		6.60	
ALBUMINE	58.8-69.6 (X)	01/04/92	62.70				63.00	
TOT. CHOLEST.	120-220 (MG/DL)	01/04/92			200.00		207.00	
TRIGLYCERIDES	50-172 (MG/DL)	01/04/92			50.00		74.00	
GLOBULINS ALPHA 1	1.8-3.8 (X)	01/04/92	3.70				3.50	
GLOBULINS ALPHA 2	3.7-13.1 (X)	01/04/92	11.80				8.60	
GLOBULINS BETA	8.9-13.6 (X)	01/04/92	12.50				11.90	
GLOBULINS GAMMA	8.4-18.3 (X)	01/04/92	9.20				13.00	
TSH	0.2-5 (UU/ML)	01/04/92	1.60					
T4	4-13 (UG/DL)	01/04/92	7.40					

1824

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 526 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/05/92		26/05/92		16/06/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/92	14.50		14.30		13.50	
HT	35-47 (%)	01/04/92	44.00		43.00		38.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	01/04/92	4.60		4.60		4.40	
RBC	4-10 (10 ⁹ /MM ³)	01/04/92	4.90		6.40		4.30	
RBC: N	45-70 (%)	01/04/92	50.00		53.00		52.00	
RBC: L	25-40 (%)	01/04/92	40.00		34.00		37.00	
RBC: E	1-4 (%)	01/04/92	2.00		3.00		3.00	
RBC: M	1-8 (%)	01/04/92	5.00		4.00		5.00	
RBC: B	0-2 (%)	01/04/92	1.00		1.00		1.00	
PLATELETS	200-300 (10 ³ /MM ³)	01/04/92	261.00		233.00		217.00	
NA+	135-144 (MMOL/L)	01/04/92	149.00	>	137.00		140.00	
K+	3.6-5.6 (MMOL/L)	01/04/92	4.56		4.00		3.90	
CL-	97-108 (MMOL/L)	01/04/92	109.00	>	103.00		106.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/92	2.39		2.46		2.40	
PO4--	0.81-1.45 (MMOL/L)	01/04/92	1.34		1.51	>	1.19	
SGOT	5-15 (U/L)	01/04/92	6.00		10.00		12.00	
SGPT	5-17 (U/L)	01/04/92	9.00		16.00		18.00	>
GAMMA GT	5-18 (U/L)	01/04/92	9.00		25.00	>	31.00	>
LDH	150-240 (U/L)	01/04/92	231.00		198.00		197.00	
ALK. PHOSPH.	60-200 (U/L)	01/04/92	97.00		122.00		110.00	
GLUCOSE	60-110 (MG/DL)	01/04/92	62.00		90.00		89.00	
BUN	10-50 (MG/DL)	01/04/92	39.00		36.00		42.00	
CREATININE	0.5-1.2 (MG/DL)	01/04/92	0.91		1.21	>	1.19	
URIC ACID	2.5-6 (MG/DL)	01/04/92	4.90		5.20		5.70	
TOT. BILIRUBIN	0.2-1 (MG/DL)	01/04/92	0.34		0.44		0.47	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/04/92	0.13					
TOT. PROTEINS	6-8 (G/DL)	01/04/92	7.00		7.10		6.60	
ALBUMINE	58.8-69.6 (%)	01/04/92	63.60				66.00	
TOT. CHOLEST.	120-220 (MG/DL)	01/04/92			316.00	>>	311.00	>>
TRIGLYCERIDES	50-172 (MG/DL)	01/04/92			317.00	>>	358.00	>>
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/04/92	3.10				3.00	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/04/92	9.00				9.20	
GLOBULINS BETA	8.9-13.6 (%)	01/04/92	12.70				13.10	
GLOBULINS GAMMA	8.4-18.3 (%)	01/04/92	11.60				8.70	
TSH	0.2-5 (UU/ML)	01/04/92	0.80					
T4	4-13 (UG/DL)	01/04/92	9.00					

1825

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/03 Patient: 527 Treatment: Imipramine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			12/05/92		09/06/92		30/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/92	13.70		13.60		13.90	
HT	35-47 (X)	01/04/92	40.00		38.00		39.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	01/04/92	4.60		4.10		4.20	
WBC	4-10 (10 ³ /MM ³)	01/04/92	4.40		9.10		9.10	
WBC: N	45-70 (X)	01/04/92	62.00		67.00		70.00	
WBC: L	25-40 (X)	01/04/92	27.00		22.00	<	20.00	
WBC: E	1-4 (X)	01/04/92	1.00		2.00		2.00	
WBC: M	1-8 (X)	01/04/92	7.00		7.00		6.00	
WBC: B	0-2 (X)	01/04/92	1.00		1.00		1.00	
PLATELETS	200-300 (10 ³ /MM ³)	01/04/92	264.00		307.00	>	307.00	
NA+	135-144 (MMOL/L)	01/04/92	141.00		126.00	<	135.00	
K+	3.6-5.6 (MMOL/L)	01/04/92	4.60		4.00		4.10	
CL-	97-108 (MMOL/L)	01/04/92	104.00		95.00	<	100.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/92	2.33		2.30		2.40	
PO4--	0.81-1.45 (MMOL/L)	01/04/92	1.05		1.11		1.19	
SGOT	5-15 (U/L)	01/04/92	7.00		6.00		8.00	
SGPT	5-17 (U/L)	01/04/92	5.00		5.00		5.00	
GAMMA GT	5-18 (U/L)	01/04/92	5.00		7.00		8.00	
LDH	150-240 (U/L)	01/04/92	159.00		162.00		168.00	
ALK. PHOSPH.	60-200 (U/L)	01/04/92	41.00	<	70.00		71.00	
GLUCOSE	60-110 (MG/DL)	01/04/92	70.00		71.00		68.00	
BUN	10-50 (MG/DL)	01/04/92	42.00		36.00		23.00	
CREATININE	0.5-1.2 (MG/DL)	01/04/92	0.96		1.01		0.97	
URIC ACID	2.5-6 (MG/DL)	01/04/92	2.00	<	4.10		4.50	
TOT. BILIRUBIN	0.2-1 (MG/DL)	01/04/92	0.27		0.40		0.48	
TOT. PROTEINS	6-8 (G/DL)	01/04/92	7.30		6.60		6.40	
ALBUMINE	58.8-69.6 (X)	01/04/92	64.60		66.50		66.00	
TOT. CHOLEST.	120-220 (MG/DL)	01/04/92	193.00		182.00		189.00	
TRIGLYCERIDES	50-172 (MG/DL)	01/04/92	41.00	<	140.00		127.00	
GLOBULINS ALPHA 1	1.8-3.8 (X)	01/04/92	2.90		5.40	>>	2.60	
GLOBULINS ALPHA 2	3.7-13.1 (X)	01/04/92	7.30		9.50		9.10	
GLOBULINS BETA	8.9-13.6 (X)	01/04/92	12.00		10.50		10.10	
GLOBULINS GAMMA	8.4-18.3 (X)	01/04/92	13.30		10.30		12.30	
TSH	0.2-5 (UU/ML)	01/04/92	0.70					
T4	4-13 (UG/DL)	01/04/92	8.10					

1826

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/03 Patient: 528 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			12/05/92	09/06/92
			value (φ)	value (φ)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/04/92	13.60	13.80
HT	35-47 (X)	01/04/92	39.00	42.00
RBC	3.8-5.2 (10 ⁶ /MM ³)	01/04/92	4.10	4.60
MBC	4-10 (10 ³ /MM ³)	01/04/92	9.80	5.00
MBC: N	45-70 (X)	01/04/92	66.00	63.00
MBC: L	25-40 (X)	01/04/92	23.00	26.00
MBC: E	1-4 (X)	01/04/92	3.00	2.00
MBC: M	1-8 (X)	01/04/92	6.00	7.00
MBC: B	0-2 (X)	01/04/92	1.00	1.00
PLATELETS	200-300 (10 ³ /MM ³)	01/04/92	278.00	259.00
NA+	135-144 (MMOL/L)	01/04/92	140.00	125.00
K+	3.6-5.6 (MMOL/L)	01/04/92	4.40	3.80
CL-	97-108 (MMOL/L)	01/04/92	100.00	93.00
Ca++	2.1-2.6 (MMOL/L)	01/04/92	2.32	2.66
PO4--	0.81-1.45 (MMOL/L)	01/04/92	1.34	1.18
SGOT	5-15 (U/L)	01/04/92	8.00	9.00
SGPT	5-17 (U/L)	01/04/92	5.00	8.00
GAMMA GT	5-18 (U/L)	01/04/92	7.00	7.00
LDH	150-240 (U/L)	01/04/92	180.00	148.00
ALK. PHOSPH.	60-200 (U/L)	01/04/92	81.00	45.00
GLUCOSE	60-110 (MG/DL)	01/04/92	81.00	75.00
BUN	10-50 (MG/DL)	01/04/92	34.00	35.00
CREATININE	0.5-1.2 (MG/DL)	01/04/92	1.03	0.95
URIC ACID	2.5-6 (MG/DL)	01/04/92	3.90	2.40
TOT. BILIRUBIN	0.2-1 (MG/DL)	01/04/92	0.27	0.42
TOT. PROTEINS	6-8 (G/DL)	01/04/92	7.00	7.00
ALBUMINE	58.8-69.6 (X)	01/04/92	64.20	63.60
TOT. CHOLEST.	120-220 (MG/DL)	01/04/92	198.00	206.00
TRIGLYCERIDES	50-172 (MG/DL)	01/04/92	125.00	40.00
GLOBULINS ALPHA 1	1.8-3.8 (X)	01/04/92	3.60	2.10
GLOBULINS ALPHA 2	3.7-13.1 (X)	01/04/92	10.40	8.60
GLOBULINS BETA	8.9-13.6 (X)	01/04/92	11.50	10.80
GLOBULINS GAMMA	8.4-18.3 (X)	01/04/92	10.40	14.90
TSH	0.2-5 (UU/ML)	01/04/92	0.70	
T4	4-13 (UG/DL)	01/04/92	6.00	

1827

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/04 Patient: 198 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/01/92		15/02/92		07/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	12/12/91	13.30		14.10		12.90	
HT	97-54 (X)	12/12/91	43.00		50.50		42.60	
RBC	3.8-5.2 (10 ⁶ /UL)	12/12/91	4.60		4.96		4.35	
WBC	4-10.8 (10 ³ /UL)	12/12/91	6.30		5.77		6.50	
WBC: N	45-70 (X)	12/12/91	59.60		65.60		57.40	
WBC: L	25-45 (X)	12/12/91	32.50		28.50		31.90	
WBC: E	1-5 (X)	12/12/91	0.50	<	0.30	<	0.90	
WBC: M	1-9 (X)	12/12/91	4.00		2.40		6.40	
WBC: B	0-2 (X)	12/12/91	1.00		1.20		1.20	
PLATELETS	150-450 (10 ³ /UL)	12/12/91	248.00		227.00		266.00	
NA+	132-151 (MMOL/L)	12/12/91	143.00		139.00		146.00	
K+	3.6-5.2 (MMOL/L)	12/12/91	4.60		5.09		5.33	
CL-	97-108 (MMOL/L)	12/12/91	102.00		104.00		102.00	
Ca++	2.2-2.65 (MMOL/L)	12/12/91	2.44		2.50		2.54	
PO4--	2.5-5 (MG/DL)	12/12/91	4.10		3.20		4.40	
SGOT	5-15 (U/L)	12/12/91	9.00		13.00		9.00	
SGPT	5-19 (U/L)	12/12/91	5.00		5.00		6.00	
GAMMA GT	5-18 (U/L)	12/12/91	14.00		17.00		13.00	
LDH	150-240 (U/L)	12/12/91	174.00		358.00	>	223.00	
ALK. PHOSPH.	65-175 (U/L)	12/12/91	135.00		143.00		120.00	
GLUCOSE	50-100 (MG/DL)	12/12/91	86.00		41.00	<	37.00	
BUN	10-50 (MG/DL)	12/12/91	39.00		34.90		43.80	
CREATININE	0.5-1 (MG/DL)	12/12/91	0.82		0.81		0.81	
URIC ACID	2.5-6 (MG/DL)	12/12/91	4.50		4.30		4.20	
TOT. BILIRUBIN	0.2-1 (MG/DL)	12/12/91	0.30		0.56		0.42	
TOT. PROTEINS	6-8.5 (G/DL)	12/12/91	7.50		8.40		7.00	
ALBUMINE	55-68 (X)	12/12/91	66.50		67.20		62.90	
TOT. CHOLEST.	120-220 (MG/DL)	12/12/91	253.00	>	259.00	>	238.00	
TRIGLYCERIDES	45-200 (MG/DL)	12/12/91	82.00		85.00		107.00	
GLOBULINS ALPHA 1	1-5 (X)	12/12/91	2.70		2.50		3.00	
GLOBULINS ALPHA 2	5-10 (X)	12/12/91	7.70		7.10		9.40	
GLOBULINS BETA	7-12 (X)	12/12/91	9.90		11.10		10.00	
GLOBULINS GAMMA	11-20 (X)	12/12/91	13.20		12.10		14.70	
TSH	0.3-3 (MU/L)	12/12/91	0.80					
T4	4.5-12 (NG/DL)	12/12/91	7.20					

1828

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/04 Patient: 194 Treatment: Roboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/01/92		15/02/92		07/03/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	12/12/91	15.70		15.30		15.70	
HT	40-54 (X)	12/12/91	48.00		52.00		50.80	
RBC	4.4-5.9 (10 ⁶ /UL)	12/12/91	5.20		5.51		5.16	
WBC	4-10.8 (10 ³ /UL)	12/12/91	4.30		5.84		5.50	
WBC: N	45-70 (X)	12/12/91	48.60		40.00 <		60.10	
WBC: L	25-45 (X)	12/12/91	38.80		56.00 >		29.70	
WBC: E	1-5 (X)	12/12/91	2.00		3.00		3.00	
WBC: M	1-9 (X)	12/12/91	7.00		1.00		3.90	
WBC: B	0-2 (X)	12/12/91	0.50		0.00		0.50	
PLATELETS	150-450 (10 ³ /UL)	12/12/91	135.00 <		149.00 <		156.00	
NA+	132-151 (MMOL/L)	12/12/91	136.00		144.00		142.00	
K+	3.6-5.2 (MMOL/L)	12/12/91	4.20		4.79		4.26	
CL-	97-108 (MMOL/L)	12/12/91	92.00 <		100.00		103.00	
Ca++	2.2-2.65 (MMOL/L)	12/12/91	2.40		2.60		2.47	
PO4--	2.5-5 (MG/DL)	12/12/91	2.96		3.60		4.00	
SGOT	5-19 (U/L)	12/12/91	28.00 >		12.00		15.00	
SGPT	5-23 (U/L)	12/12/91	68.00 >>		22.00		36.00 >	
GAMMA GT	5-28 (U/L)	12/12/91	11.00		24.00		9.00	
LDH	150-240 (U/L)	12/12/91	230.00		171.00		189.00	
ALK. PHOSPH.	65-175 (U/L)	12/12/91	162.00		165.00		123.00	
GLUCOSE	50-100 (MG/DL)	12/12/91	102.00 >		96.00		56.00	
BUN	10-50 (MG/DL)	12/12/91	35.00		37.20		34.30	
CREATININE	0.6-1.1 (MG/DL)	12/12/91	0.83		1.07		0.84	
URIC ACID	3.5-7 (MG/DL)	12/12/91	5.00		7.00		4.30	
TOT BILIRUBIN	0.2-1 (MG/DL)	12/12/91	1.43 >		0.47		1.18 >	
DIR BILIRUBIN	0-0.3 (MG/DL)	12/12/91	0.25		0.20		0.20	
TOT. PROTEINS	6-8.5 (G/DL)	12/12/91	7.80		8.30		7.90	
ALBUMINE	55-68 (X)	12/12/91	62.10		69.40 >		71.00 >	
TOT. CHOLEST.	120-220 (MG/DL)	12/12/91	175.00		222.00 >		180.00	
TRIGLYCERIDES	45-200 (MG/DL)	12/12/91	74.00		425.00 >>		140.00	
GLOBULINS ALPHA 1	1-5 (X)	12/12/91	2.90		2.60		1.60	
GLOBULINS ALPHA 2	5-10 (X)	12/12/91	7.10		5.90		5.30	
GLOBULINS BETA	7-12 (X)	12/12/91	10.50		9.10		6.30 <	
GLOBULINS GAMMA	11-20 (X)	12/12/91	17.40		13.00		15.80	
TSH	0.3-3 (MU/L)	12/12/91	1.20					
T4	4.5-12 (NG/DL)	12/12/91	7.20					

1829

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/04 Patient: 195 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/01/92		15/02/92		07/03/92	
			value	(☺)	value	(☺)	value	(☺)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	12/12/91	14.60		14.70		14.10	
HT	37-54 (%)	12/12/91	45.00		44.80		45.20	
RBC	3.8-5.2 (10 ⁶ /UL)	12/12/91	5.00		4.52		4.66	
WBC	4-10.8 (10 ³ /UL)	12/12/91	9.40		8.46		9.50	
WBC: N	45-70 (%)	12/12/91	49.10		56.90		39.20 <	
WBC: L	25-45 (%)	12/12/91	40.50		37.50		52.40 >	
WBC: E	1-5 (%)	12/12/91	1.80		0.70 <		0.90 <	
WBC: M	1-9 (%)	12/12/91	5.70		1.90		3.10	
WBC: B	0-2 (%)	12/12/91	0.80		1.10		0.80	
PLATELETS	150-450 (10 ³ /UL)	12/12/91	290.00		306.00		264.00	
NA+	132-151 (MMOL/L)	12/12/91	136.00		141.00		142.00	
K+	3.6-5.2 (MMOL/L)	12/12/91	4.20		5.33 >		4.65	
CL-	97-108 (MMOL/L)	12/12/91	90.00 <		100.00		101.00	
Ca++	2.2-2.65 (MMOL/L)	12/12/91	2.42		2.56		2.39	
PO4--	2.5-5 (MG/DL)	12/12/91	4.70		7.20 >>		6.80 >>	
SGOT	5-15 (U/L)	12/12/91	8.00		9.00		8.00	
SGPT	5-19 (U/L)	12/12/91	6.00		8.00		9.00	
GAMMA GT	5-18 (U/L)	12/12/91	11.00		19.00 >		11.00	
LDH	150-240 (U/L)	12/12/91	233.00		307.00 >		207.00	
ALK. PHOSPH.	65-175 (U/L)	12/12/91	90.00		152.00		88.00	
GLUCOSE	50-100 (MG/DL)	12/12/91	98.00		89.00		61.00	
BUN	10-50 (MG/DL)	12/12/91	43.00		25.90		44.30	
CREATININE	0.5-1 (MG/DL)	12/12/91	0.90		0.92		0.86	
URIC ACID	2.5-6 (MG/DL)	12/12/91	4.80		5.50		4.50	
TOT. BILIRUBIN	0.2-1 (MG/DL)	12/12/91	0.49		0.77		0.33	
TOT. PROTEINS	6-8.5 (G/DL)	12/12/91	7.60		8.00		7.30	
ALBUMINE	55-68 (%)	12/12/91	61.60		70.50 >		63.80	
TOT. CHOLEST.	120-220 (MG/DL)	12/12/91	356.00 >>		232.00 >		327.00 >>	
TRIGLYCERIDES	45-200 (MG/DL)	12/12/91	166.00		214.00 >		173.00	
GLOBULINS ALPHA 1	1-5 (%)	12/12/91	2.20		2.80		2.20	
GLOBULINS ALPHA 2	5-10 (%)	12/12/91	9.40		7.70		9.40	
GLOBULINS BETA	7-12 (%)	12/12/91	10.70		9.00		9.40	
GLOBULINS GAMMA	11-20 (%)	12/12/91	16.10		10.00 <		15.20	
TSH	0.3-3 (MU/L)	12/12/91	0.80					
T4	4.5-12 (NG/DL)	12/12/91	7.80					

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1830

(☺) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/04 Patient: 196 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/02/92		22/02/92		14/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	12/12/91	12.60		12.30		12.90	
HT	37-54 (X)	12/12/91	38.80		39.50		37.80	
RBC	3.8-5.2 (10 ⁶ /UL)	12/12/91	4.40		4.32		4.60	
WBC	4-10.8 (10 ³ /UL)	12/12/91	3.90 <		4.21		5.35	
WBC: N	45-70 (%)	12/12/91	42.00 <		59.40		60.00	
WBC: L	25-45 (%)	12/12/91	48.00 >		25.70		36.00	
WBC: E	1-5 (X)	12/12/91	0.00 <		3.30		2.00	
WBC: M	1-9 (X)	12/12/91	10.00 >		7.90		2.00	
WBC: B	0-2 (X)	12/12/91	0.00		1.00		0.00	
PLATELETS	150-450 (10 ³ /UL)	12/12/91	262.00		234.00		231.00	
NA+	132-151 (MMOL/L)	12/12/91	141.00		143.00		140.00	
K+	3.6-5.2 (MMOL/L)	12/12/91	3.95		5.58 >		4.00	
CL-	97-108 (MMOL/L)	12/12/91	100.00		97.00		100.00	
Ca++	2.2-2.65 (MMOL/L)	12/12/91	2.49		2.42		2.39	
PO4--	2.5-5 (MG/DL)	12/12/91	3.33		3.84		3.40	
SGOT	5-15 (U/L)	12/12/91	9.00		12.00		9.00	
SGPT	5-19 (U/L)	12/12/91	14.00		12.00		14.00	
GAMMA GT	5-18 (U/L)	12/12/91	15.00		11.00		44.00 >>	
LDH	150-240 (U/L)	12/12/91	184.00		353.00 >		223.00	
ALK. PHOSPH.	65-175 (U/L)	12/12/91	124.00		128.00		212.00 >	
GLUCOSE	50-100 (MG/DL)	12/12/91	91.00		98.00		51.00	
BUN	10-50 (MG/DL)	12/12/91	32.80		41.80		37.10	
CREATININE	0.5-1 (MG/DL)	12/12/91	0.82		0.71		0.67	
URIC ACID	2.5-6 (MG/DL)	12/12/91	5.10		4.80		3.00	
TOT. BILIRUBIN	0.2-1 (MG/DL)	12/12/91	0.43		0.35		0.52	
TOT. PROTEINS	6-8.5 (G/DL)	12/12/91	7.10		7.40		7.20	
ALBUMINE	55-68 (%)	12/12/91	68.40 >		68.10 >		65.70	
TOT. CHOLEST.	120-220 (MG/DL)	12/12/91	195.00		194.00		216.00	
TRIGLYCERIDES	45-200 (MG/DL)	12/12/91	59.00		61.00		170.00	
GLOBULINS ALPHA 1	1-5 (X)	12/12/91	2.30		2.10		2.50	
GLOBULINS ALPHA 2	5-10 (X)	12/12/91	6.30		8.20		5.30	
GLOBULINS BETA	7-12 (X)	12/12/91	9.50		8.00		11.40	
GLOBULINS GAMMA	11-20 (X)	12/12/91	13.50		13.60		15.10	
TSH	0.3-3 (MU/L)	12/12/91	2.10					
T4	4.5-12 (NG/DL)	12/12/91	7.40					

1831

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/04 Patient: 197 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/02/92		22/02/92		14/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	12/12/91	16.60		15.90		16.00	
HT	40-54 (%)	12/12/91	50.00		49.60		48.50	
RBC	4.4-5.9 (10 ⁶ /UL)	12/12/91	5.74		5.09		5.69	
WBC	4-10.8 (10 ³ /UL)	12/12/91	6.08		5.66		6.21	
WBC: N	45-70 (%)	12/12/91	67.80		79.80	>	62.60	
WBC: L	25-45 (%)	12/12/91	23.50	<	15.00	<<	30.60	
WBC: E	1-5 (%)	12/12/91	2.60		0.80	<	0.90	
WBC: M	1-9 (%)	12/12/91	3.80		2.50		3.90	
WBC: B	0-2 (%)	12/12/91	0.80		0.50		0.60	
PLATELETS	150-450 (10 ³ /UL)	12/12/91	242.00		186.00		319.00	
NA+	132-151 (MMOL/L)	12/12/91	144.00		142.00		141.00	
K+	3.6-5.2 (MMOL/L)	12/12/91	3.79		4.20		5.21	
CL-	97-108 (MMOL/L)	12/12/91	106.00		98.00		98.00	
Ca++	2.2-2.65 (MMOL/L)	12/12/91	2.43		2.43		2.57	
PO4--	2.5-5 (MG/DL)	12/12/91	2.96		3.68		2.60	
SGOT	5-19 (U/L)	12/12/91	9.00		8.00		10.00	
SGPT	5-23 (U/L)	12/12/91	11.00		7.00		15.00	
GAMMA GT	5-28 (U/L)	12/12/91	11.00		13.00		15.00	
LDH	150-240 (U/L)	12/12/91	146.00	<	235.00		252.00	
ALK. PHOSPH.	65-175 (U/L)	12/12/91	115.00		99.00		111.00	
GLUCOSE	50-100 (MG/DL)	12/12/91	121.00	>	79.00		68.00	
BUN	10-50 (MG/DL)	12/12/91	24.00		29.50		31.00	
CREATININE	0.6-1.1 (MG/DL)	12/12/91	1.18	>	1.06		0.75	
URIC ACID	3.5-7 (MG/DL)	12/12/91	5.70		5.00		5.80	
TOT. BILIRUBIN	0.2-1 (MG/DL)	12/12/91	0.96		0.57		1.17	
TOT. PROTEINS	6-8.5 (G/DL)	12/12/91	7.40		6.40		7.90	
ALBUMINE	55-68 (%)	12/12/91	73.90	>	65.70		68.80	
TOT. CHOLEST.	120-220 (MG/DL)	12/12/91	183.00		166.00		186.00	
TRIGLYCERIDES	45-200 (MG/DL)	12/12/91	198.00		56.00		100.00	
GLOBULINS ALPHA 1	1-5 (%)	12/12/91	1.10		2.60		2.20	
GLOBULINS ALPHA 2	5-10 (%)	12/12/91	3.90	<	7.70		5.50	
GLOBULINS BETA	7-12 (%)	12/12/91	8.00		8.40		9.90	
GLOBULINS GAMMA	11-20 (%)	12/12/91	13.10		15.60		13.60	
TSH	0.3-3 (MU/L)	12/12/91	0.10	<<				
T4	4.5-12 (NG/DL)	12/12/91	9.60					

1832

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/04 Patient: 198 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/02/92		22/02/92		14/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	12/12/91	14.00		14.70		14.10	
HT	37-54 (%)	12/12/91	44.70		50.50		49.00	
RBC	3.8-5.2 (10 ⁶ /UL)	12/12/91	4.93		4.91		4.80	
HBC	4-10.8 (10 ³ /UL)	12/12/91	6.22		6.35		6.10	
HBC: N	45-70 (%)	12/12/91	51.80		57.10		56.90	
HBC: L	25-45 (%)	12/12/91	37.00		35.80		35.80	
HBC: E	1-5 (%)	12/12/91	1.30		1.70		1.70	
HBC: M	1-9 (%)	12/12/91	4.80		2.00		2.00	
HBC: B	0-2 (%)	12/12/91	0.50		1.50		1.60	
PLATELETS	150-450 (10 ³ /UL)	12/12/91	271.00		178.00		170.00	
NA+	132-151 (MMOL/L)	12/12/91	140.00		141.00		142.00	
K+	3.6-5.2 (MMOL/L)	12/12/91	3.67				5.30 >	
CL-	97-108 (MMOL/L)	12/12/91	98.00		100.00		102.00 >	
Ca++	2.2-2.65 (MMOL/L)	12/12/91	2.43		2.52		2.60	
PO4--	2.5-5 (MG/DL)	12/12/91	3.50		3.93		3.70	
SGOT	5-15 (U/L)	12/12/91	7.00		9.00		11.00	
SGPT	5-19 (U/L)	12/12/91	3.00 <		12.00		10.00	
GAMMA GT	5-18 (U/L)	12/12/91	9.00		9.00		10.00	
LDH	150-240 (U/L)	12/12/91	158.00		244.00 >		239.00	
ALK. PHOSPH.	65-175 (U/L)	12/12/91	81.00		106.00		105.00	
GLUCOSE	50-100 (MG/DL)	12/12/91	101.00 >		89.00		91.00	
BUN	10-50 (MG/DL)	12/12/91	25.00		27.50		44.50	
CREATININE	0.5-1 (MG/DL)	12/12/91	0.81		0.92		0.81	
URIC ACID	2.5-6 (MG/DL)	12/12/91	3.00		2.70		5.00	
TOT. BILIRUBIN	0.2-1 (MG/DL)	12/12/91	0.28		0.61		0.48	
TOT. PROTEINS	6-8.5 (G/DL)	12/12/91	7.60		7.90		7.80	
ALBUMINE	55-68 (%)	12/12/91	69.80 >		64.90		64.90	
TOT. CHOLEST.	120-220 (MG/DL)	12/12/91	259.00 >		277.00 >		231.00 >	
TRIGLYCERIDES	45-200 (MG/DL)	12/12/91	163.00		140.00		180.00	
GLOBULINS ALPHA 1	1-5 (%)	12/12/91	2.70		2.40		2.30	
GLOBULINS ALPHA 2	5-10 (%)	12/12/91	6.50		9.50		9.40	
GLOBULINS BETA	7-12 (%)	12/12/91	8.90		6.10 <		6.20 <	
GLOBULINS GAMMA	11-20 (%)	12/12/91	12.10		17.10		16.90	
TSH	0.3-3 (MU/L)	12/12/91	1.80					
T4	4.5-12 (NG/DL)	12/12/91	8.80					

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1833

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/04 Patient: 199 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/03/92		18/04/92		09/05/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12.8-17 (G/DL)	20/03/92	13.90		14.20		14.30	
HT	39-53 (X)	20/03/92	41.00		42.00		44.00	
RBC	4.2-5.7 (10 ⁶ /UL)	20/03/92	4.60		4.50		4.70	
WBC	4.5-10 (10 ³ /UL)	20/03/92	9.00		8.60		8.60	
WBC: N	45-70 (X)	20/03/92	66.00		64.00		65.00	
WBC: L	25-45 (X)	20/03/92	24.00	<	27.00		25.00	
WBC: E	1-5 (X)	20/03/92	5.00		4.00		4.00	
WBC: M	1-9 (X)	20/03/92	4.00		3.00		6.00	
WBC: B	0-2 (X)	20/03/92	1.00		2.00		0.00	
PLATELETS	130-300 (10 ³ /UL)	20/03/92	232.00		214.00		276.00	
NA+	133-149 (MMOL/L)	20/03/92	143.00		140.00		141.00	
K+	3.7-5 (MMOL/L)	20/03/92	4.10		3.90		4.30	
CL-	96-106 (MMOL/L)	20/03/92	103.00		99.00		100.00	
Ca++	2.2-2.7 (MMOL/L)	20/03/92	2.50		2.50		2.30	
PO4--	2.4-5.1 (MG/DL)	20/03/92	4.10		5.10		4.30	
SGOT	5-20 (U/L)	20/03/92	14.00		11.00		11.00	
SGPT	5-23 (U/L)	20/03/92	16.00		13.00		14.00	
GAMMA GT	5-27 (U/L)	20/03/92	11.00		14.00		20.00	
LDH	150-230 (U/L)	20/03/92	200.00		180.00		187.00	
ALK. PHOSPH.	60-180 (U/L)	20/03/92	151.00		160.00		97.00	
GLUCOSE	45-105 (MG/DL)	20/03/92	88.00		86.00		81.00	
BUN	8-55 (MG/DL)	20/03/92	33.00		31.00		11.00	
CREATININE	0.5-1.2 (MG/DL)	20/03/92	0.60		0.70		0.60	
URIC ACID	4-6.9 (MG/DL)	20/03/92	5.50		5.10		7.00	>
TOT BILIRUBIN	0.2-1 (MG/DL)	20/03/92	0.60		0.30		0.80	
DIR BILIRUBIN	0-0.35 (MG/DL)	20/03/92	0.20		0.10		0.30	
TOT. PROTEINS	5.8-8.7 (G/DL)	20/03/92	7.30		7.20		6.10	
ALBUMINE	52-70 (X)	20/03/92	67.00		65.00		68.00	
TOT. CHOLEST.	120-220 (MG/DL)	20/03/92	255.00	>	270.00	>	201.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/03/92	230.00	>	234.00	>	209.00	>
GLOBULINS ALPHA 1	1-5 (X)	20/03/92	1.10		2.00		4.40	
GLOBULINS ALPHA 2	5-11 (X)	20/03/92	8.00		7.50		10.80	
GLOBULINS BETA	6-12 (X)	20/03/92	11.00		12.00		6.60	
GLOBULINS GAMMA	10-20 (X)	20/03/92	12.90		13.50		10.20	
TSH	0.2-3.1 (MU/L)	20/03/92	2.10					
T4	4.3-12.5 (NG/DL)	20/03/92	8.00					

1834

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/04 Patient: 200 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/03/92		18/04/92		09/05/92	
			value	(♣)	value	(♣)	value	(♣)
Laboratory test	Range value	Range date						
HB	12.8-17 (G/DL)	20/03/92	14.10		14.40		14.30	
HT	39-53 (%)	20/03/92	45.00		45.00		46.00	
RBC	4.2-5.7 (10 ⁶ /UL)	20/03/92	4.60		4.50		4.70	
NBC	4.5-10 (10 ³ /UL)	20/03/92	8.70		7.90		7.90	
NBC: N	45-70 (%)	20/03/92	66.00		64.00		64.00	
NBC: L	25-45 (%)	20/03/92	22.00	<	23.00	<	23.00	<
NBC: E	1-5 (%)	20/03/92	3.00		3.00		4.00	
NBC: M	1-9 (%)	20/03/92	8.00		9.00		9.00	
NBC: B	0-2 (%)	20/03/92	1.00		1.00		0.00	
PLATELETS	130-300 (10 ³ /UL)	20/03/92	273.00		258.00		266.00	
NA+	133-149 (MMOL/L)	20/03/92	141.00		144.00		142.00	
K+	3.7-5 (MMOL/L)	20/03/92	4.40		4.30		4.30	
CL-	96-106 (MMOL/L)	20/03/92	101.00		100.00		98.00	
Ca++	2.2-2.7 (MMOL/L)	20/03/92	2.60		2.50		2.40	
PO4--	2.4-5.1 (MG/DL)	20/03/92	4.80		4.70		3.10	
SGOT	5-20 (U/L)	20/03/92	21.00	>	19.00		9.00	
SGPT	5-23 (U/L)	20/03/92	20.00		18.00		11.00	
GAMMA GT	5-27 (U/L)	20/03/92	14.00		15.00		12.00	
LDH	150-230 (U/L)	20/03/92	156.00		149.00	<	171.00	
ALK. PHOSPH.	60-180 (U/L)	20/03/92	110.00		112.00		91.00	
GLUCOSE	45-105 (MG/DL)	20/03/92	78.00		81.00		86.00	
BUN	8-55 (MG/DL)	20/03/92	11.00		22.00		14.00	
CREATININE	0.5-1.2 (MG/DL)	20/03/92	0.70		0.60		0.70	
URIC ACID	4-6.9 (MG/DL)	20/03/92	7.10	>	7.60	>	7.10	>
TOT. BILIRUBIN	0.2-1 (MG/DL)	20/03/92	0.60		0.50		0.80	
DIR. BILIRUBIN	0-0.35 (MG/DL)	20/03/92	0.20		0.20		0.20	
TOT. PROTEINS	5.8-8.7 (G/DL)	20/03/92	6.80		6.90		7.00	
ALBUMINE	52-70 (%)	20/03/92	66.00		65.00		68.00	
TOT. CHOLEST.	120-220 (MG/DL)	20/03/92	231.00	>	211.00		231.00	>
TRIGLYCERIDES	45-200 (MG/DL)	20/03/92	188.00		201.00	>	176.00	
GLOBULINS ALPHA 1	1-5 (%)	20/03/92	4.00		2.00		3.00	
GLOBULINS ALPHA 2	5-11 (%)	20/03/92	6.00		7.00		5.00	
GLOBULINS BETA	6-12 (%)	20/03/92	10.00		11.00		9.00	
GLOBULINS GAMMA	10-20 (%)	20/03/92	14.00		15.00		15.00	
TSH	0.2-3.1 (MU/L)	20/03/92	0.25					
T4	4.3-12.5 (NG/DL)	20/03/92	4.90					

1835

(♣) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range.
 < out of range (value lower than min range) > out of range (value higher than max range.
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/04 Patient: 201 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/03/92		18/04/92		09/05/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-15.5 (G/DL)	20/03/92	12.60		12.90		12.80	
HT	36-55 (X)	20/03/92	41.00		42.00		42.00	
RBC	3.7-5.2 (10 ⁶ /UL)	20/03/92	4.10		4.00		4.20	
HBC	4.5-10 (10 ³ /UL)	20/03/92	7.00		6.80		6.80	
HBC: N	45-70 (X)	20/03/92	62.00		59.00		60.00	
HBC: L	25-45 (X)	20/03/92	24.00	<	26.00		26.00	
HBC: E	1-5 (X)	20/03/92	4.00		4.00		5.00	
HBC: M	1-9 (X)	20/03/92	8.00		9.00		8.00	
HBC: B	0-2 (X)	20/03/92	2.00		2.00		1.00	
PLATELETS	130-300 (10 ³ /UL)	20/03/92	248.00		273.00		253.00	
NA+	133-149 (MMOL/L)	20/03/92	143.00		143.00		141.00	
K+	3.7-5 (MMOL/L)	20/03/92	4.80		4.60		4.10	
CL-	96-106 (MMOL/L)	20/03/92	100.00		97.00		100.00	
Ca++	2.2-2.7 (MMOL/L)	20/03/92	2.30		2.60		2.40	
PO4--	2.4-5.1 (MG/DL)	20/03/92	4.10		4.30		3.00	
SGOT	5-16 (U/L)	20/03/92	11.00		8.00		11.00	
SGPT	5-20 (U/L)	20/03/92	8.00		14.00		14.00	
GAMMA GT	5-20 (U/L)	20/03/92	12.00		9.00		12.00	
LDH	150-230 (U/L)	20/03/92	204.00		209.00		210.00	
ALK. PHOSPH.	60-180 (U/L)	20/03/92	117.00		61.00		110.00	
GLUCOSE	45-105 (MG/DL)	20/03/92	100.00		91.00		91.00	
BUN	8-55 (MG/DL)	20/03/92	33.00		11.00		33.00	
CREATININE	0.4-1 (MG/DL)	20/03/92	0.80		0.70		0.70	
URIC ACID	3-6 (MG/DL)	20/03/92	6.30	>	5.90		6.80	>
TOT BILIRUBIN	0.2-1 (MG/DL)	20/03/92	0.50		0.60		0.60	
DIR BILIRUBIN	0-0.35 (MG/DL)	20/03/92	0.20		0.20		0.30	
TOT. PROTEINS	5.8-8.7 (G/DL)	20/03/92	7.10		7.30		7.20	
ALBUMINE	52-70 (X)	20/03/92	68.00		66.00		67.00	
TOT. CHOLEST.	120-220 (MG/DL)	20/03/92	271.00	>	244.00	>	213.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/03/92	198.00		231.00	>	230.00	>
GLOBULINS ALPHA 1	1-5 (X)	20/03/92	3.00		5.00		4.00	
GLOBULINS ALPHA 2	5-11 (X)	20/03/92	10.00		10.00		9.00	
GLOBULINS BETA	6-12 (X)	20/03/92	9.00		10.00		8.00	
GLOBULINS GAMMA	10-20 (X)	20/03/92	10.00		9.00	<	12.00	
TSH	0.2-3.1 (MU/L)	20/03/92	1.10					
T4	4.3-12.5 (NG/DL)	20/03/92	8.10					

1836

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/04 Patient: 202 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/04/92		25/04/92		16/05/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12.8-17 (G/DL)	20/03/92	15.10		14.90		14.90	
HT	39-53 (X)	20/03/92	49.00		48.00		47.00	
RBC	4.2-5.7 (10 ⁶ /UL)	20/03/92	4.80		5.20		4.70	
WBC	4.5-10 (10 ³ /UL)	20/03/92	6.80		7.10		7.10	
WBC: N	45-70 (X)	20/03/92	67.00		66.00		65.00	
WBC: L	25-45 (X)	20/03/92	26.00		25.00		27.00	
WBC: E	1-5 (X)	20/03/92	3.00		4.00		3.00	
WBC: M	1-9 (X)	20/03/92	3.00		3.00		3.00	
WBC: B	0-2 (X)	20/03/92	1.00		2.00		2.00	
PLATELETS	130-300 (10 ³ /UL)	20/03/92	211.00		235.00		210.00	
NA+	133-149 (MMOL/L)	20/03/92	141.00		140.00		140.00	
K+	3.7-5 (MMOL/L)	20/03/92	4.20		4.40		4.20	
CL-	96-106 (MMOL/L)	20/03/92	98.00		99.00		97.00	
Ca++	2.2-2.7 (MMOL/L)	20/03/92	2.60		2.50		2.50	
PO4--	2.4-5.1 (MG/DL)	20/03/92	3.00		2.90		3.00	
SGOT	5-20 (U/L)	20/03/92	19.00		12.00		17.00	
SGPT	5-23 (U/L)	20/03/92	18.00		15.00		14.00	
GAMMA GT	5-27 (U/L)	20/03/92	16.00		10.00		15.00	
LDH	150-230 (U/L)	20/03/92	104.00	<	181.00		98.00	
ALK. PHOSPH.	60-180 (U/L)	20/03/92	88.00		76.00		93.00	
GLUCOSE	45-105 (MG/DL)	20/03/92	77.00		81.00		109.00	
BUN	8-55 (MG/DL)	20/03/92	18.00		17.00		17.00	
CREATININE	0.5-1.2 (MG/DL)	20/03/92	0.60		0.60		0.50	
URIC ACID	4-6.9 (MG/DL)	20/03/92	6.60		6.30		6.40	
TOT BILIRUBIN	0.2-1 (MG/DL)	20/03/92	0.40		0.40		0.40	
DIR BILIRUBIN	0-0.35 (MG/DL)	20/03/92	0.20		0.20		0.20	
TOT. PROTEINS	5.8-8.7 (G/DL)	20/03/92	7.10		8.00		7.30	
ALBUMINE	52-70 (X)	20/03/92	66.00		63.00		65.00	
TOT. CHOLEST.	120-220 (MG/DL)	20/03/92	214.00		198.00		213.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/03/92	205.00	>	190.00		181.00	
GLOBULINS ALPHA 1	1-5 (X)	20/03/92	4.00		5.00		5.00	
GLOBULINS ALPHA 2	5-11 (X)	20/03/92	10.00		10.00		9.00	
GLOBULINS BETA	6-12 (X)	20/03/92	8.00		8.00		8.00	
GLOBULINS GAMMA	10-20 (X)	20/03/92	12.00		14.00		13.00	
TSH	0.2-3.1 (MU/L)	20/03/92	2.40					
T4	4.3-12.5 (NG/DL)	20/03/92	5.60					

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(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/04 Patient: 203 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/04/92		25/04/92		16/05/92	
			value	(±)	value	(±)	value	(±)
Laboratory test	Range value	Range date						
HB	11.5-15.5 (G/DL)	20/03/92	13.10		13.30		13.10	
HT	36-55 (%)	20/03/92	43.00		44.00		43.00	
RBC	3.7-5.2 (10 ⁶ /UL)	20/03/92	4.20		4.30		4.10	
HBC	4.5-10 (10 ³ /UL)	20/03/92	7.30		6.90		8.10	
HBC: N	45-70 (%)	20/03/92	62.00		63.00		64.00	
HBC: L	25-45 (%)	20/03/92	27.00		26.00		27.00	
HBC: E	1-5 (%)	20/03/92	4.00		4.00		4.00	
HBC: M	1-9 (%)	20/03/92	5.00		4.00		3.00	
HBC: B	0-2 (%)	20/03/92	2.00		3.00	>>	2.00	
PLATELETS	130-300 (10 ³ /UL)	20/03/92	201.00		255.00		241.00	
NA+	133-149 (MMOL/L)	20/03/92	141.00		142.00		143.00	
K+	3.7-5 (MMOL/L)	20/03/92	4.20		4.30		4.20	
CL-	96-106 (MMOL/L)	20/03/92	95.00	<	100.00		103.00	
Ca++	2.2-2.7 (MMOL/L)	20/03/92	2.60		2.50		2.78	
PO4--	2.4-5.1 (MG/DL)	20/03/92	2.70		4.90		4.30	
SGOT	5-16 (U/L)	20/03/92	9.00		14.00		11.00	
SGPT	5-20 (U/L)	20/03/92	8.00		12.00		7.00	
GAMMA GT	5-20 (U/L)	20/03/92	12.00		17.00		15.00	
LDH	150-230 (U/L)	20/03/92	88.00	<	200.00		94.00	
ALK. PHOSPH.	60-180 (U/L)	20/03/92	77.00		120.00		133.00	
GLUCOSE	45-105 (MG/DL)	20/03/92	100.00		76.00		71.00	
BUN	8-55 (MG/DL)	20/03/92	22.00		34.00		23.00	
CREATININE	0.4-1 (MG/DL)	20/03/92	0.50		0.50		0.40	
URIC ACID	3-6 (MG/DL)	20/03/92	6.10	>	6.80	>	7.10	
TOT. BILIRUBIN	0.2-1 (MG/DL)	20/03/92	0.40		0.30		0.40	
DIR BILIRUBIN	0-0.35 (MG/DL)	20/03/92	0.10		0.10		0.10	
TOT. PROTEINS	5.8-8.7 (G/DL)	20/03/92	6.90		7.00		6.90	
ALBUMINE	52-70 (g)	20/03/92	67.00		62.00		64.00	
TOT. CHOLEST.	120-220 (MG/DL)	20/03/92	188.00		179.00		180.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/03/92	204.00	>	211.00	>	203.00	
GLOBULINS ALPHA 1	1-5 (%)	20/03/92	4.00		5.00		4.00	
GLOBULINS ALPHA 2	5-11 (%)	20/03/92	9.00		10.00		11.00	
GLOBULINS BETA	6-12 (%)	20/03/92	7.00		9.00		10.00	
GLOBULINS GAMMA	10-20 (%)	20/03/92	13.00		14.00		11.00	
TSH	0.2-3.1 (MU/L)	20/03/92	2.60					
T4	4.3-12.5 (NG/DL)	20/03/92	6.10					

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(±) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCDL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/04 Patient: 204 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/04/92		25/04/92		16/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-15.5 (G/DL)	20/03/92	12.10		12.40		12.30	
HT	36-55 (X)	20/03/92	41.00		42.00		42.00	
RBC	3.7-5.2 (10 ⁶ /UL)	20/03/92	3.90		4.00		4.10	
WBC	4.5-10 (10 ³ /UL)	20/03/92	6.10		7.00		7.10	
WBC: N	45-70 (X)	20/03/92	65.00		66.00		64.00	
WBC: L	25-45 (X)	20/03/92	24.00	<	23.00	<	23.00	
WBC: E	1-5 (X)	20/03/92	3.00		4.00		5.00	
WBC: M	1-9 (X)	20/03/92	6.00		5.00		5.00	
WBC: B	0-2 (X)	20/03/92	2.00		2.00		3.00	
PLATELETS	130-300 (10 ³ /UL)	20/03/92	210.00		279.00		266.00	
NA+	133-149 (MMOL/L)	20/03/92	140.00		143.00		141.00	
K+	3.7-5 (MMOL/L)	20/03/92	4.00		4.20		4.30	
CL-	96-106 (MMOL/L)	20/03/92	100.00		98.00		88.00	
Ca++	2.2-2.7 (MMOL/L)	20/03/92	2.50		2.40		2.50	
PO4--	2.4-5.1 (MG/DL)	20/03/92	3.20		3.30		3.70	
SGOT	5-16 (U/L)	20/03/92	11.00		12.00		11.00	
SGPT	5-20 (U/L)	20/03/92	16.00		8.00		14.00	
GAMMA GT	5-20 (U/L)	20/03/92	14.00		11.00		9.00	
LDH	150-230 (U/L)	20/03/92	190.00		188.00		122.00	
ALK. PHOSPH.	60-180 (U/L)	20/03/92	75.00		97.00		96.00	
GLUCOSE	45-105 (MG/DL)	20/03/92	90.00		81.00		83.00	
BUN	8-55 (MG/DL)	20/03/92	21.00		21.00		21.00	
CREATININE	0.4-1 (MG/DL)	20/03/92	0.40		0.40		0.50	
URIC ACID	3-6 (MG/DL)	20/03/92	6.10	>	7.10	>	6.80	
TOT BILIRUBIN	0.2-1 (MG/DL)	20/03/92	0.40		0.40		0.30	
DIR BILIRUBIN	0-0.35 (MG/DL)	20/03/92	0.20		0.10		0.10	
TOT. PROTEINS	5.8-8.7 (G/DL)	20/03/92	7.10		7.20		6.90	
ALBUMINE	52-70 (X)	20/03/92	70.00		67.00		66.00	
TOT. CHOLEST.	120-220 (MG/DL)	20/03/92	190.00		214.00		201.00	
TRIGLYCERIDES	45-200 (MG/DL)	20/03/92	181.00		171.00		187.00	
GLOBULINS ALPHA 1	1-5 (X)	20/03/92	4.00		5.00		5.00	
GLOBULINS ALPHA 2	5-11 (X)	20/03/92	6.00		7.00		8.00	
GLOBULINS BETA	6-12 (X)	20/03/92	8.00		9.00		9.00	
GLOBULINS GAMMA	10-20 (X)	20/03/92	12.00		12.00		12.00	
TSH	0.2-3.1 (MU/L)	20/03/92	0.90					
T4	4.3-12.5 (NG/DL)	20/03/92	4.50					

1839

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/05 Patient: 205 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/12/91		17/02/92		09/03/92	
			value	(±)	value	(±)	value	(±)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	23/12/91	16.30		16.40		16.00	
HT	40-54 (Z)	23/12/91	48.00		46.00		46.00	
RBC	4-5.9 (10 ⁶ /MM ³)	23/12/91	5.20		5.60		7.20 >	
WBC	4-9 (10 ³ /MM ³)	23/12/91	7.20		6.40		6.10	
WBC: N	50-70 (Z)	23/12/91	61.00		58.00		60.00	
WBC: L	25-40 (Z)	23/12/91	29.00		31.00		30.00	
WBC: E	2-4 (Z)	23/12/91	3.00		3.00		3.00	
WBC: M	2-6 (Z)	23/12/91	6.00		7.00 >		6.00	
WBC: B	0-1 (Z)	23/12/91	1.00		1.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	287.00		271.00		246.00	
NA+	135-145 (MMOL/L)	23/12/91	142.00		138.00		141.00	
K+	3-5 (MMOL/L)	23/12/91	4.70		4.50		4.70	
CL-	96-107 (MMOL/L)	23/12/91	102.00		100.00		101.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.48		2.41		2.56	
PO4--	2.5-5 (MG/DL)	23/12/91	3.60		4.10		4.90	
SGOT	5-18 (U/L)	23/12/91	12.00		8.00		10.00	
SGPT	5-22 (U/L)	23/12/91	14.00		12.00		6.00	
GAMMA GT	5-28 (U/L)	23/12/91	19.00		19.00		14.00	
LDH	120-240 (U/L)	23/12/91	189.00		210.00		196.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	141.00		117.00		121.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	87.00		81.00		87.00	
BUN	10-50 (MG/DL)	23/12/91	29.00		31.00		32.00	
CREATININE	0.6-1.1 (MG/DL)	23/12/91	1.00		1.00		1.00	
URIC ACID	3.6-7 (MG/DL)	23/12/91	4.10		3.80		3.40 <	
TOT BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.60		0.50		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.10		0.10		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	7.40		7.80		7.60	
ALBUMINE	55-68 (Z)	23/12/91	62.00		63.00		60.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	189.00		176.00		184.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	151.00		142.00		158.00	
GLOBULINS ALPHA 1	1-5 (Z)	23/12/91	3.00		4.00		6.00 >	
GLOBULINS ALPHA 2	5-10 (Z)	23/12/91	7.00		9.00		9.00	
GLOBULINS BETA	7-12 (Z)	23/12/91	10.00		8.00		10.00	
GLOBULINS GAMMA	11-20 (Z)	23/12/91	18.00		16.00		15.00	
TSH	0.3-3 (MU/L)	23/12/91	2.10					
T4	4.5-11.5 (UG/DL)	23/12/91	7.30					

1840

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/05 Patient: 206 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/01/92		18/02/92		10/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	23/12/91	14.10		14.40		14.60	
HT	36-50 (X)	23/12/91	39.00		38.00		39.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	23/12/91	4.10		4.30		4.50	
WBC	4-9 (10 ³ /MM ³)	23/12/91	5.20		5.90		6.20	
WBC: N	50-70 (X)	23/12/91	65.00		64.00		63.00	
WBC: L	25-40 (X)	23/12/91	28.00		30.00		29.00	
WBC: E	2-4 (X)	23/12/91	2.00		2.00		3.00	
WBC: M	2-6 (X)	23/12/91	4.00		4.00		4.00	
WBC: B	0-1 (X)	23/12/91	1.00		0.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	212.00		183.00		214.00	
NA+	135-145 (MMOL/L)	23/12/91	142.00		139.00		141.00	
K+	3.6-5 (MMOL/L)	23/12/91	3.90		4.20		4.40	
CL-	96-107 (MMOL/L)	23/12/91	97.00		101.00		102.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.29		2.37		2.65	
PO4--	2.5-5 (MG/DL)	23/12/91	2.90		3.30		3.60	
SGOT	5-16 (U/L)	23/12/91	8.00		10.00		14.00	
SGPT	5-18 (U/L)	23/12/91	10.00		8.00		12.00	
GAMMA GT	5-20 (U/L)	23/12/91	10.00		14.00		19.00	
LDH	120-240 (U/L)	23/12/91	153.00		169.00		187.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	161.00		124.00		102.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	78.00		81.00		76.00	
BUN	10-50 (MG/DL)	23/12/91	32.00		33.00		36.00	
CREATININE	0.5-0.9 (MG/DL)	23/12/91	0.70		0.70		0.70	
URIC ACID	2.4-6 (MG/DL)	23/12/91	2.90		3.20		3.90	
TOT BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.40		0.50		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.10		0.10		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	6.90		7.10		7.30	
ALBUMINE	55-68 (X)	23/12/91	62.00		64.00		62.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	157.00		162.00		182.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	161.00		127.00		174.00	
GLOBULINS ALPHA 1	1-5 (X)	23/12/91	4.00		4.00		3.00	
GLOBULINS ALPHA 2	5-10 (X)	23/12/91	10.00		6.00		9.00	
GLOBULINS BETA	7-12 (X)	23/12/91	10.00		10.00		9.00	
GLOBULINS GAMMA	11-20 (X)	23/12/91	14.00		16.00		17.00	
TSH	0.3-3 (MU/L)	23/12/91	1.70					
T4	4.5-11.5 (UG/DL)	23/12/91	6.20					

1841

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/05 Patient: 207 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/01/92		18/02/92		10/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	23/12/91	14.70		14.30		13.80	
HT	36-50 (%)	23/12/91	41.00		40.00		39.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	23/12/91	4.60		4.30		4.50	
HBC	4-9 (10 ³ /MM ³)	23/12/91	7.10		6.30		5.80	
HBC: N	50-70 (%)	23/12/91	62.00		63.00		61.00	
HBC: L	25-40 (%)	23/12/91	30.00		31.00		33.00	
HBC: E	2-4 (%)	23/12/91	2.00		1.00 <		2.00	
HBC: M	2-6 (%)	23/12/91	5.00		4.00		3.00	
HBC: B	0-1 (%)	23/12/91	1.00		1.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	312.00		283.00		250.00	
NA+	135-145 (MMOL/L)	23/12/91	139.00		137.00		139.00	
K+	3.6-5 (MMOL/L)	23/12/91	3.90		3.80		4.00	
CL-	96-107 (MMOL/L)	23/12/91	101.00		97.00		99.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.52		2.61		2.46	
PO4--	2.5-5 (MG/DL)	23/12/91	4.10		4.40		3.20	
SGOT	5-16 (U/L)	23/12/91	12.00		10.00		8.00	
SGPT	5-18 (U/L)	23/12/91	10.00		10.00		10.00	
GAMMA GT	5-20 (U/L)	23/12/91	19.00		19.00		13.00	
LDH	120-240 (U/L)	23/12/91	187.00		203.00		184.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	96.00		83.00		97.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	81.00		77.00		81.00	
BUN	10-50 (MG/DL)	23/12/91	36.00		33.00		31.00	
CREATININE	0.5-0.9 (MG/DL)	23/12/91	0.70		0.70		0.70	
URIC ACID	2.4-6 (MG/DL)	23/12/91	3.20		2.90		4.60	
TOT BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.40		0.70		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.10		0.20		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	6.90		7.00		6.90	
ALBUMINE	55-68 (%)	23/12/91	62.00		63.00		65.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	147.00		129.00		136.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	158.00		151.00		147.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	2.00		3.00		3.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	8.00		7.00		6.00	
GLOBULINS BETA	7-12 (%)	23/12/91	9.00		9.00		9.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	19.00		18.00		17.00	
TSH	0.3-3 (MU/L)	23/12/91	2.70					
T4	4.5-11.5 (UG/DL)	23/12/91	8.60					

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1842

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value and laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/05 Patient: 208 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/01/92		20/02/92		12/03/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	23/12/91	17.30		16.90		17.10	
HT	40-54 (%)	23/12/91	49.00		48.00		47.00	
RBC	4-5.9 (10 ⁶ /MM ³)	23/12/91	4.70		5.00		5.20	
HBC	4-9 (10 ³ /MM ³)	23/12/91	5.50		6.70		6.40	
HBC: N	50-70 (%)	23/12/91	63.00		62.00		63.00	
HBC: L	25-40 (%)	23/12/91	29.00		33.00		30.00	
HBC: E	2-4 (%)	23/12/91	2.00		1.00	<	2.00	
HBC: H	2-6 (%)	23/12/91	5.00		4.00		4.00	
HBC: B	0-1 (%)	23/12/91	1.00		0.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	281.00		252.00		238.00	
NA+	135-145 (MMOL/L)	23/12/91	142.00		140.00		142.00	
K+	3-5 (MMOL/L)	23/12/91	4.70		4.50		4.10	
CL-	96-107 (MMOL/L)	23/12/91	102.00		101.00		99.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.55		2.43		2.40	
PO4--	2.5-5 (MG/DL)	23/12/91	3.10		3.70		4.20	
SGOT	5-18 (U/L)	23/12/91	12.00		12.00		10.00	
SGPT	5-22 (U/L)	23/12/91	12.00		10.00		10.00	
GAMMA GT	5-28 (U/L)	23/12/91	19.00		15.00		14.00	
LDH	120-240 (U/L)	23/12/91	221.00		200.00		182.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	158.00		149.00		116.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	72.00		82.00		74.00	
BUN	10-50 (MG/DL)	23/12/91	37.00		35.00		34.00	
CREATININE	0.6-1.1 (MG/DL)	23/12/91	0.90		1.00		1.00	
URIC ACID	3.6-7 (MG/DL)	23/12/91	4.70		4.30		4.00	
TOT. BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.60		0.70		0.60	
DIR. BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.20		0.20		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	8.10		8.00		8.20	
ALBUMINE	55-68 (%)	23/12/91	64.00		63.00		62.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	202.00		189.00		177.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	186.00		156.00		162.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	3.00		4.00		4.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	9.00		7.00		8.00	
GLOBULINS BETA	7-12 (%)	23/12/91	8.00		10.00		11.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	16.00		16.00		15.00	
TSH	0.3-3 (MU/L)	23/12/91	1.20					
T4	4.5-11.5 (UG/DL)	23/12/91	5.30					

1843

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/05 Patient: 209 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			29/01/92		26/02/92		18/03/92	
			value	(é)	value	(é)	value	(é)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	23/12/91	16.90		17.20		17.60	
HT	40-54 (%)	23/12/91	47.00		49.00		51.00	
RBC	4-5.9 (10~6/MM3)	23/12/91	4.90		5.40		5.60	
WBC	4-9 (10~3/MM3)	23/12/91	6.30		6.70		6.90	
WBC: N	50-70 (%)	23/12/91	62.00		61.00		62.00	
WBC: L	25-40 (%)	23/12/91	33.00		34.00		33.00	
WBC: E	2-4 (%)	23/12/91	2.00		1.00	<	2.00	
WBC: M	2-6 (%)	23/12/91	3.00		4.00		3.00	
WBC: B	0-1 (%)	23/12/91	0.00		0.00		0.00	
PLATELETS	150-400 (10~3/MM3)	23/12/91	194.00		214.00		164.00	
NA+	135-145 (MMOL/L)	23/12/91	142.00		139.00		141.00	
K+	3-5 (MMOL/L)	23/12/91	4.30		4.50		4.10	
CL-	96-107 (MMOL/L)	23/12/91	104.00		103.00		102.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.59		2.41		2.46	
PO4--	2.5-5 (MG/DL)	23/12/91	4.30		4.00		3.70	
SGOT	5-18 (U/L)	23/12/91	12.00		12.00		12.00	
SGPT	5-22 (U/L)	23/12/91	16.00		15.00		13.00	
GAMMA GT	5-28 (U/L)	23/12/91	22.00		21.00		19.00	
LDH	120-240 (U/L)	23/12/91	181.00		209.00		164.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	126.00		112.00		153.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	83.00		78.00		94.00	
BUN	10-50 (MG/DL)	23/12/91	35.00		37.00		34.00	
CREATININE	0.6-1.1 (MG/DL)	23/12/91	1.00		1.10		1.00	
URIC ACID	3.6-7 (MG/DL)	23/12/91	5.10		5.90		6.20	
TOT BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.70		0.60		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.20		0.10		0.20	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	8.20		8.30		8.10	
ALBUMINE	55-68 (%)	23/12/91	66.00		64.00		62.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	219.00		197.00		212.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	180.00		163.00		183.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	5.00		3.00		3.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	7.00		5.00		8.00	
GLOBULINS BETA	7-12 (%)	23/12/91	8.00		11.00		9.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	14.00		17.00		18.00	
TSH	0.3-3 (MU/L)	23/12/91	2.10					
T4	4.5-11.5 (UG/DL)	23/12/91	8.30					

1844

(é) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/05 Patient: 210 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/02/92		28/02/92		20/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	23/12/91	16.40		16.90		16.40	
HT	40-54 (%)	23/12/91	45.00		47.00		45.00	
RBC	4-5.9 (10 ⁶ /MM ³)	23/12/91	4.50		5.00		5.20	
HBC	4-9 (10 ³ /MM ³)	23/12/91	4.80		5.80		7.50	
HBC: N	50-70 (%)	23/12/91	58.00		60.00		59.00	
HBC: L	25-40 (%)	23/12/91	33.00		33.00		32.00	
HBC: E	2-4 (%)	23/12/91	2.00		8.00	>>	2.00	
HBC: H	2-6 (%)	23/12/91	6.00		4.00		6.00	
HBC: B	0-1 (%)	23/12/91	1.00		1.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	259.00		288.00		243.00	
NA+	135-145 (MMOL/L)	23/12/91	142.00		143.00		141.00	
K+	3-5 (MMOL/L)	23/12/91	4.10		4.70		4.10	
CL-	96-107 (MMOL/L)	23/12/91	98.00		97.00		99.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.41		2.50		2.27	
PO4--	2.5-5 (MG/DL)	23/12/91	3.70		4.10		4.70	
SGOT	5-18 (U/L)	23/12/91	12.00		16.00		12.00	
SGPT	5-22 (U/L)	23/12/91	10.00		12.00		16.00	
GAMMA GT	5-28 (U/L)	23/12/91	16.00		22.00		21.00	
LDH	120-240 (U/L)	23/12/91	180.00		191.00		216.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	125.00		149.00		132.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	98.00		84.00		76.00	
BUN	10-50 (MG/DL)	23/12/91	31.00		32.00		36.00	
CREATININE	0.6-1.4 (MG/DL)	23/12/91	1.00		1.00		1.10	
URIC ACID	3.6-7 (MG/DL)	23/12/91	3.70		5.90		5.20	
TOT. BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.70		0.60		0.60	
DIR. BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.20		0.10		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	8.10		8.30		8.20	
ALBUMINE	55-68 (%)	23/12/91	62.00		60.00		62.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	199.00		214.00		184.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	156.00		143.00		130.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	3.00		3.00		2.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	7.00		7.00		9.00	
GLOBULINS BETA	7-12 (%)	23/12/91	11.00		11.00		10.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	17.00		19.00		17.00	
TSH	0.3-3 (MU/L)	23/12/91	2.10					
T4	4.5-11.5 (UG/DL)	23/12/91	5.90					

1845

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/05 Patient: 541 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/03/92		07/04/92		28/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	23/12/91	12.70		12.30		12.40	
HT	36-50 (%)	23/12/91	41.00		42.00		42.00	
RBC	3.8-5.2 (10 ⁶ /MM3)	23/12/91	4.60		4.30		4.50	
WBC	4-9 (10 ³ /MM3)	23/12/91	5.50		6.20		6.50	
WBC: N	50-70 (%)	23/12/91	62.00		60.00		62.00	
WBC: L	25-40 (%)	23/12/91	31.00		33.00		33.00	
WBC: E	2-4 (%)	23/12/91	2.00		2.00		1.00 <	
WBC: M	2-6 (%)	23/12/91	4.00		4.00		4.00	
WBC: B	0-1 (%)	23/12/91	1.00		1.00		0.00	
PLATELETS	150-400 (10 ³ /MM3)	23/12/91	217.00		243.00		255.00	
NA+	135-145 (MMOL/L)	23/12/91	142.00		140.00		141.00	
K+	3.6-5 (MMOL/L)	23/12/91	4.30		4.10		4.00	
CL-	96-107 (MMOL/L)	23/12/91	103.00		100.00		101.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.49		2.29		2.24	
PO4--	2.5-5 (MG/DL)	23/12/91	3.60		3.10		2.90	
SGOT	5-16 (U/L)	23/12/91	8.00		10.00		10.00	
SGPT	5-18 (U/L)	23/12/91	10.00		12.00		10.00	
GAMMA GT	5-20 (U/L)	23/12/91	10.00		15.00		14.00	
LDH	120-240 (U/L)	23/12/91	184.00		173.00		199.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	97.00		101.00		141.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	84.00		78.00		79.00	
BUN	10-50 (MG/DL)	23/12/91	32.00		33.00		29.00	
CREATININE	0.5-0.9 (MG/DL)	23/12/91	0.80		0.70		0.70	
URIC ACID	2.4-6 (MG/DL)	23/12/91	4.00		3.80		3.00	
TOT. BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.70		0.60		0.60	
DIR. BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.20		0.10		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	7.60		7.30		7.50	
ALBUMINE	55-68 (%)	23/12/91	61.00		64.00		62.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	180.00		203.00		187.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	159.00		165.00		153.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	4.00		2.00		5.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	8.00		9.00		9.00	
GLOBULINS BETA	7-12 (%)	23/12/91	9.00		10.00		10.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	18.00		15.00		14.00	
TSH	0.3-3 (MU/L)	23/12/91	1.70					
T4	4.5-11.5 (UG/DL)	23/12/91	8.90					

1846

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/05 Patient: 542 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/03/92		07/04/92		28/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	23/12/91	16.30		16.90		17.30	
HT	40-54 (%)	23/12/91	49.00		51.00		50.00	
RBC	4-5.9 (10 ⁶ /MM ³)	23/12/91	5.20		4.90		5.40	
WBC	4-9 (10 ³ /MM ³)	23/12/91	7.30		7.00		6.80	
WBC: N	50-70 (%)	23/12/91	62.00		64.00		62.00	
WBC: L	25-40 (%)	23/12/91	29.00		30.00		30.00	
WBC: E	2-4 (%)	23/12/91	3.00		2.00		3.00	
WBC: M	2-6 (%)	23/12/91	5.00		4.00		4.00	
WBC: B	0-1 (%)	23/12/91	1.00		1.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	361.00		347.00		368.00	
NA+	135-145 (MMOL/L)	23/12/91	144.00		142.00		144.00	
K+	3-5 (MMOL/L)	23/12/91	4.80		4.60		4.80	
CL-	96-107 (MMOL/L)	23/12/91	103.00		105.00		104.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.23		2.41		2.47	
PO4--	2.5-5 (MG/DL)	23/12/91	4.00		3.80		4.10	
SGOT	5-18 (U/L)	23/12/91	14.00		16.00		14.00	
SGPT	5-22 (U/L)	23/12/91	19.00		12.00		15.00	
GAMMA GT	5-28 (U/L)	23/12/91	22.00		24.00		21.00	
LDH	120-240 (U/L)	23/12/91	214.00		226.00		197.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	146.00		129.00		136.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	89.00		76.00		76.00	
BUN	10-50 (MG/DL)	23/12/91	38.00		41.00		39.00	
CREATININE	0.6-1.1 (MG/DL)	23/12/91	1.00		1.00		1.00	
URIC ACID	3.6-7 (MG/DL)	23/12/91	4.90		5.60		4.40	
TOT BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.80		0.70		0.80	
DIR BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.20		0.20		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	8.30		8.20		8.00	
ALBUMINE	55-68 (%)	23/12/91	63.00		64.00		60.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	216.00		184.00		197.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	159.00		126.00		146.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	4.00		3.00		4.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	7.00		9.00		6.00	
GLOBULINS BETA	7-12 (%)	23/12/91	9.00		10.00		11.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	17.00		14.00		19.00	
TSH	0.3-3 (MU/L)	23/12/91	1.90					
T4	4.5-11.5 (UG/DL)	23/12/91	8.30					

1847

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/05 Patient: 543 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/03/92		08/04/92		29/04/92	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	23/12/91	17.20		17.40		17.00	
HT	40-54 (%)	23/12/91	52.00		51.00		49.00	
RBC	4-5.9 (10 ⁶ /MM ³)	23/12/91	5.50		5.80		5.20	
WBC	4-9 (10 ³ /MM ³)	23/12/91	7.60		8.10		6.20	
WBC: N	50-70 (%)	23/12/91	63.00		62.00		60.00	
WBC: L	25-40 (%)	23/12/91	33.00		33.00		34.00	
WBC: E	2-4 (%)	23/12/91	2.00		3.00		2.00	
WBC: M	2-6 (%)	23/12/91	2.00		2.00		3.00	
WBC: B	0-1 (%)	23/12/91	0.00		0.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	226.00		280.00		307.00	
NA+	135-145 (MMOL/L)	23/12/91	138.00		141.00		137.00	
K+	3-5 (MMOL/L)	23/12/91	4.00		4.20		3.90	
CL-	96-107 (MMOL/L)	23/12/91	101.00		97.00		98.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.49		2.36		2.55	
PO4--	2.5-5 (MG/DL)	23/12/91	2.80		3.10		4.70	
SGOT	5-18 (U/L)	23/12/91	10.00		9.00		11.00	
SGPT	5-22 (U/L)	23/12/91	9.00		10.00		18.00	
GAMMA GT	5-28 (U/L)	23/12/91	13.00		15.00		22.00	
LDH	120-240 (U/L)	23/12/91	197.00		184.00		167.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	87.00		101.00		142.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	95.00		92.00		103.00	
BUN	10-50 (MG/DL)	23/12/91	39.00		42.00		41.00	
CREATININE	0.6-1.1 (MG/DL)	23/12/91	1.10		1.10		1.10	
URIC ACID	3.6-7 (MG/DL)	23/12/91	6.10		5.80		4.70	
TOT. BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.80		0.70		0.70	
DIR. BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.20		0.10		0.20	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	8.30		8.20		8.40	
ALBUMINE	55-68 (%)	23/12/91	64.00		63.00		67.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	174.00		162.00		173.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	89.00		100.00		97.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	2.00		2.00		2.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	8.00		8.00		6.00	
GLOBULINS BETA	7-12 (%)	23/12/91	9.00		7.00		10.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	17.00		20.00		15.00	
TSH	0.3-3 (MU/L)	23/12/91	1.60					
T4	4.5-11.5 (UG/DL)	23/12/91	9.30					

1848

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/05 Patient: 544 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/03/92		14/04/92		05/05/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HR	12-16 (G/DL)	23/12/91	13.60		13.30		13.00	
HT	36-50 (%)	23/12/91	39.00		41.00		42.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	23/12/91	4.10		4.30		4.40	
WBC	4-9 (10 ³ /MM ³)	23/12/91	5.00		6.90		6.20	
WBC: N	50-70 (%)	23/12/91	58.00		59.00		61.00	
WBC: L	25-40 (%)	23/12/91	36.00		33.00		31.00	
WBC: E	2-4 (%)	23/12/91	2.00		2.00		3.00	
WBC: M	2-6 (%)	23/12/91	3.00		5.00		4.00	
WBC: B	0-1 (%)	23/12/91	1.00		1.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	187.00		207.00		298.00	
NA+	135-145 (MMOL/L)	23/12/91	136.00		139.00		140.00	
K+	3.6-5 (MMOL/L)	23/12/91	4.60		4.20		3.90	
CL-	96-107 (MMOL/L)	23/12/91	99.00		101.00		104.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.50		2.41		2.49	
PO4--	2.5-5 (MG/DL)	23/12/91	3.70		3.40		4.00	
SGOT	5-16 (U/L)	23/12/91	9.00		6.00		11.00	
SGPT	5-18 (U/L)	23/12/91	6.00		6.00		8.00	
GAMMA GT	5-20 (U/L)	23/12/91	8.00		9.00		16.00	
LDH	120-240 (U/L)	23/12/91	184.00		170.00		204.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	123.00		142.00		144.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	104.00		99.00		75.00	
BUN	10-50 (MG/DL)	23/12/91	37.00		35.00		32.00	
CREATININE	0.5-0.9 (MG/DL)	23/12/91	0.70		0.60		0.60	
URIC ACID	2.4-6 (MG/DL)	23/12/91	3.10		2.90		3.80	
TOT BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.60		0.60		0.50	
DIR BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.10		0.10		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	7.40		7.00		6.70	
ALBUMINE	55-68 (%)	23/12/91	63.00		62.00		60.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	166.00		146.00		154.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	187.00		160.00		149.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	2.00		3.00		4.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	9.00		8.00		7.00	
GLOBULINS BETA	7-12 (%)	23/12/91	10.00		9.00		11.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	16.00		18.00		18.00	
TSH	0.3-3 (MU/L)	23/12/91	2.10					
T4	4.5-11.5 (UG/DL)	23/12/91	8.90					

1849

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/05 Patient: 545 Treatment: Placebo Sex: Male

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			09/03/92		15/04/92		06/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	23/12/91	15.90		16.20		16.90	
HT	40-54 (%)	23/12/91	52.00		50.00		52.00	
RBC	4-5.9 (10 ⁶ /MM ³)	23/12/91	5.30		5.00		5.30	
WBC	4-9 (10 ³ /MM ³)	23/12/91	7.80		7.20		8.10	
WBC: N	50-70 (%)	23/12/91	62.00		63.00		64.00	
WBC: L	25-40 (%)	23/12/91	31.00		33.00		29.00	
WBC: E	2-4 (%)	23/12/91	2.00		2.00		2.00	
WBC: M	2-6 (%)	23/12/91	4.00		2.00		5.00	
WBC: B	0-1 (%)	23/12/91	1.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	279.00		243.00		179.00	
NA+	135-145 (MMOL/L)	23/12/91	144.00		142.00		145.00	
K+	3-5 (MMOL/L)	23/12/91	3.90		4.10		4.70	
CL-	96-107 (MMOL/L)	23/12/91	99.00		102.00		100.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.49		2.55		2.61	
PO4--	2.5-5 (MG/DL)	23/12/91	4.60		4.20		4.70	
SGOT	5-18 (U/L)	23/12/91	14.00		14.00		16.00	
SGPT	5-22 (U/L)	23/12/91	19.00		12.00		19.00	
GAMMA GT	5-28 (U/L)	23/12/91	26.00		19.00		26.00	
LDH	120-240 (U/L)	23/12/91	219.00		236.00		219.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	143.00		119.00		154.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	86.00		80.00		72.00	
BUN	10-50 (MG/DL)	23/12/91	35.00		41.00		43.00	
CREATININE	0.6-1.1 (MG/DL)	23/12/91	1.00		1.10		1.10	
URIC ACID	3.6-7 (MG/DL)	23/12/91	6.10		5.80		6.30	
TOT BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.60		0.60		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.10		0.20		0.20	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	8.00		8.30		8.00	
ALBUMINE	55-68 (%)	23/12/91	63.00		64.00		67.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	198.00		182.00		200.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	200.00		194.00		177.00	
GLOBULINS ALPHA 1	1-5 (%)	23/12/91	4.00		3.00		3.00	
GLOBULINS ALPHA 2	5-10 (%)	23/12/91	6.00		6.00		8.00	
GLOBULINS BETA	7-12 (%)	23/12/91	10.00		9.00		8.00	
GLOBULINS GAMMA	11-20 (%)	23/12/91	17.00		18.00		14.00	
TSH	0.3-3 (MU/L)	23/12/91	0.98					
T4	4.5-11.5 (UG/DL)	23/12/91	10.10					

1850

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/05 Patient: 546 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/03/92		15/04/92		06/05/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	23/12/91	13.10		13.60		13.30	
HT	36-50 (X)	23/12/91	41.00		43.00		41.00	
RBC	3.8-5.2 (10 ⁶ /MM ³)	23/12/91	4.50		4.60		4.20	
HBC	4-9 (10 ³ /MM ³)	23/12/91	6.30		5.70		6.00	
HBC: N	50-70 (X)	23/12/91	62.00		63.00		61.00	
HBC: L	25-40 (X)	23/12/91	31.00		33.00		30.00	
HBC: E	2-4 (X)	23/12/91	3.00		2.00		3.00	
HBC: M	2-6 (X)	23/12/91	4.00		2.00		5.00	
HBC: B	0-1 (X)	23/12/91	0.00		0.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	23/12/91	189.00		200.00		241.00	
NA+	135-145 (MMOL/L)	23/12/91	141.00		139.00		136.00	
K+	3.6-5 (MMOL/L)	23/12/91	4.60		4.40		4.00	
CL-	96-107 (MMOL/L)	23/12/91	103.00		101.00		99.00	
Ca++	2.2-2.65 (MMOL/L)	23/12/91	2.39		2.22		2.28	
PO4--	2.5-5 (MG/DL)	23/12/91	3.10		3.60		3.10	
SGOT	5-16 (U/L)	23/12/91	8.00		6.00		8.00	
SGPT	5-18 (U/L)	23/12/91	9.00		6.00		10.00	
GAMMA GT	5-20 (U/L)	23/12/91	6.00		9.00		17.00	
LDH	120-240 (U/L)	23/12/91	231.00		209.00		184.00	
ALK. PHOSPH.	60-170 (U/L)	23/12/91	154.00		141.00		109.00	
GLUCOSE	70-120 (MG/DL)	23/12/91	88.00		93.00		81.00	
BUN	10-50 (MG/DL)	23/12/91	34.00		38.00		38.00	
CREATININE	0.5-0.9 (MG/DL)	23/12/91	0.70		0.70		0.80	
URIC ACID	2.4-6 (MG/DL)	23/12/91	3.90		3.40		3.80	
TOT BILIRUBIN	0.2-1 (MG/DL)	23/12/91	0.60		0.70		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	23/12/91	0.10		0.20		0.10	
TOT. PROTEINS	6-8.5 (G/DL)	23/12/91	6.90		7.00		7.40	
ALBUMINE	55-68 (X)	23/12/91	64.00		63.00		61.00	
TOT. CHOLEST.	120-220 (MG/DL)	23/12/91	194.00		174.00		162.00	
TRIGLYCERIDES	45-200 (MG/DL)	23/12/91	165.00		144.00		113.00	
GLOBULINS ALPHA 1	1-5 (X)	23/12/91	4.00		4.00		3.00	
GLOBULINS ALPHA 2	5-10 (X)	23/12/91	8.00		9.00		8.00	
GLOBULINS BETA	7-12 (X)	23/12/91	9.00		10.00		11.00	
GLOBULINS GAMMA	11-20 (X)	23/12/91	15.00		14.00		17.00	
TSH	0.3-3 (MU/L)	23/12/91	1.60					
T4	4.5-11.5 (UG/DL)	23/12/91	8.30					

1851

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/07 Patient: 529 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/02/92		10/03/92		31/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	28/11/91	12.10		12.80		13.10	
HT	37-54 (%)	28/11/91	41.20		39.90		31.20 <<	
RBC	3.8-5.2 (10 ⁶ /UL)	28/11/91	4.13		4.15		4.21	
WBC	4-10.8 (10 ³ /UL)	28/11/91	5.39		4.91		4.88	
WBC: N	45-70 (%)	28/11/91	46.40		74.00 >		49.00	
WBC: L	25-45 (%)	28/11/91	40.50		21.00 <		41.70	
WBC: E	1-5 (%)	28/11/91	5.40	>	1.00		2.50	
WBC: M	1-9 (%)	28/11/91	3.90		3.00		2.90	
WBC: B	0-2 (%)	28/11/91	0.70		1.00		3.50 >>	
PLATELETS	150-450 (10 ³ /UL)	28/11/91	177.00		165.00		185.00	
NA+	132-151 (MMOL/L)	28/11/91	140.00		141.00		143.00	
K+	3.6-5.2 (MMOL/L)	28/11/91	6.53 >>		4.47		6.56 >>	
CL-	97-108 (MMOL/L)	28/11/91	100.00		98.00		98.00	
Ca++	2.2-2.65 (MMOL/L)	28/11/91	2.38		2.33		2.29	
PO4--	2.5-5 (MG/DL)	28/11/91	4.30		4.30		4.20	
SGOT	5-15 (U/L)	28/11/91	8.00		7.00		9.00	
SGPT	5-19 (U/L)	28/11/91	7.00		8.00		7.00	
GAMMA GT	5-18 (U/L)	28/11/91	8.00		9.00		9.00	
LDH	120-240 (U/L)	28/11/91	198.00		184.00		206.00	
ALK. PHOSPH.	65-175 (U/L)	28/11/91	73.00		82.00		86.00	
GLUCOSE	50-100 (MG/DL)	28/11/91	86.00		86.00		104.00 >	
CREATININE	0.5-0.9 (MG/DL)	28/11/91	0.66		0.70		0.74	
URIC ACID	2.5-6 (MG/DL)	28/11/91	3.50		3.70		3.70	
TOT BILIRUBIN	0.2-1 (MG/DL)	28/11/91	0.46		0.58		0.55	
TOT. PROTEINS	6-8.5 (G/DL)	28/11/91	6.50		6.90		7.20	
ALBUMINE	55-60 (%)	28/11/91	71.40 >		68.90 >		69.70 >	
TOT. CHOLEST.	120-220 (MG/DL)	28/11/91	284.00 >		283.00 >		265.00 >	
TRIGLYCERIDES	45-200 (MG/DL)	28/11/91	197.00		95.00		160.00	
GLOBULINS ALPHA 1	1-5 (%)	28/11/91	2.20		2.30		2.50	
GLOBULINS ALPHA 2	5-10 (%)	28/11/91	7.10		7.80		8.30	
GLOBULINS BETA	7-12 (%)	28/11/91	7.10		7.90		7.20	
GLOBULINS GAMMA	11-20 (%)	28/11/91	12.20		13.10		12.30	
TSH	0.3-3 (MU/L)	28/11/91	2.60					
T4	4.5-12 (NG/DL)	28/11/91	6.60					

1852

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/07 Patient: 530 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			17/02/92
			value (±)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	28/11/91	13.90
HT	37-54 (%)	28/11/91	43.00
RBC	3.8-5.2 (10 ⁶ /UL)	28/11/91	5.20
WBC	4-10.8 (10 ³ /UL)	28/11/91	5.98
WBC: N	45-70 (%)	28/11/91	46.00
WBC: L	25-45 (%)	28/11/91	43.00
WBC: E	1-5 (%)	28/11/91	3.20
WBC: M	1-9 (%)	28/11/91	4.60
WBC: B	0-2 (%)	28/11/91	0.60
PLATELETS	150-450 (10 ³ /UL)	28/11/91	270.00
NA+	132-154 (MMOL/L)	28/11/91	146.00
K+	3.6-5.2 (MMOL/L)	28/11/91	4.62
CL-	97-108 (MMOL/L)	28/11/91	98.00
Ca++	2.2-2.65 (MMOL/L)	28/11/91	2.59
PO4--	2.5-5 (MG/DL)	28/11/91	3.70
SGOT	5-15 (U/L)	28/11/91	10.00
SGPT	5-19 (U/L)	28/11/91	13.00
GAMMA GT	5-18 (U/L)	28/11/91	11.00
LDH	120-240 (U/L)	28/11/91	211.00
ALK. PHOSPH.	65-175 (U/L)	28/11/91	110.00
GLUCOSE	50-100 (MG/DL)	28/11/91	86.00
CREATININE	0.5-0.9 (MG/DL)	28/11/91	0.69
URIC ACID	2.5-6 (MG/DL)	28/11/91	3.90
TOT BILIRUBIN	0.2-1 (MG/DL)	28/11/91	1.03 >
DIR BILIRUBIN	0-0.3 (MG/DL)	28/11/91	0.12
TOT. PROTEINS	6-8.5 (G/DL)	28/11/91	8.20
ALBUMINE	55-60 (%)	28/11/91	64.00 >
TOT. CHOLEST.	120-220 (MG/DL)	28/11/91	225.00 >
TRIGLYCERIDES	45-200 (MG/DL)	28/11/91	83.00
GLOBULINS ALPHA 1	1-5 (%)	28/11/91	2.40
GLOBULINS ALPHA 2	5-10 (%)	28/11/91	6.00
GLOBULINS BETA	7-12 (%)	28/11/91	11.30
GLOBULINS GAMMA	11-20 (%)	28/11/91	16.30
TSH	0.3-3 (MU/L)	28/11/91	0.70
T4	4.5-12 (NG/DL)	28/11/91	9.60

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(±) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/07 Patient: 531 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/02/92		17/03/92		06/04/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	28/11/91	12.60		13.40			
HT	37-54 (%)	28/11/91	41.20		43.70			
RBC	3.8-5.2 (10 ⁶ /UL)	28/11/91	4.75		4.88			
WBC	4-10.8 (10 ³ /UL)	28/11/91	5.90		4.74			
WBC: N	45-70 (%)	28/11/91	49.20		56.50			
WBC: L	25-45 (%)	28/11/91	40.60		32.50			
WBC: E	1-5 (%)	28/11/91	2.30		1.80			
WBC: M	1-9 (%)	28/11/91	3.80		4.50			
WBC: B	0-2 (%)	28/11/91	0.80		0.70			
PLATELETS	150-450 (10 ³ /UL)	28/11/91	198.00		209.00			
NA+	132-151 (MMOL/L)	28/11/91	138.00		140.00	144.00		
K+	3.6-5.2 (MMOL/L)	28/11/91	5.40 >		4.90	5.02		
CL-	97-108 (MMOL/L)	28/11/91	84.00 <<		90.00 <	88.00 <		
Ca++	2.2-2.65 (MMOL/L)	28/11/91	2.42		2.51	2.57		
PO4--	2.5-5 (MG/DL)	28/11/91	3.20		3.20	2.80		
SGOT	5-15 (U/L)	28/11/91	10.00		10.00	11.00		
SGPT	5-19 (U/L)	28/11/91	4.00 <		15.00	11.00		
GAMMA GT	5-18 (U/L)	28/11/91	14.00		17.00	15.00		
LDH	120-240 (U/L)	28/11/91	189.00		242.00 >	254.00 >		
ALK. PHOSPH.	65-175 (U/L)	28/11/91	106.00		129.00	109.00		
GLUCOSE	50-100 (MG/DL)	28/11/91	127.00 >		151.00 >>	146.00 >>		
CREATININE	0.5-0.9 (MG/DL)	28/11/91	0.43 <		0.60	0.47 <		
URIC ACID	2.5-6 (MG/DL)	28/11/91	5.10		5.90	5.80		
TOT. BILIRUBIN	0.2-1 (MG/DL)	28/11/91	0.50		0.26	0.46		
TOT. PROTEINS	6-8.5 (G/DL)	28/11/91	7.50		8.20	7.90		
ALBUMINE	55-60 (%)	28/11/91	63.80 >		64.10 >	60.60 >		
TOT. CHOLEST.	120-220 (MG/DL)	28/11/91	261.00 >		304.00 >>	282.00 >		
TRIGLYCERIDES	45-200 (MG/DL)	28/11/91	225.00 >		380.00 >>	186.00		
GLOBULINS ALPHA 1	1-5 (%)	28/11/91	3.00		2.80	3.30		
GLOBULINS ALPHA 2	5-10 (%)	28/11/91	9.20		9.00	11.50 >		
GLOBULINS BETA	7-12 (%)	28/11/91	8.70		8.90	9.50		
GLOBULINS GAMMA	11-20 (%)	28/11/91	15.30		15.20	15.10		
TSH	0.3-3 (MU/L)	28/11/91	2.10					
T4	4.5-12 (NG/DL)	28/11/91	8.40					

1854

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/07 Patient: 532 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/04/92		18/05/92		09/06/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	28/11/91	13.50		14.60		14.30	
HT	37-54 (X)	28/11/91	42.70		47.70		45.90	
RBC	3.8-5.2 (10 ⁶ /UL)	28/11/91	3.93		4.05		4.11	
WBC	4-10.8 (10 ³ /UL)	28/11/91	4.54		8.03		6.51	
WBC: N	45-70 (X)	28/11/91	57.90		84.50	>	61.40	
WBC: L	25-45 (X)	28/11/91	32.50		10.50	<<	28.90	
WBC: E	1-5 (X)	28/11/91	1.70		0.50	<	1.10	
WBC: M	1-9 (X)	28/11/91	4.50		2.40		5.90	
WBC: B	0-2 (X)	28/11/91	1.10		1.10		1.00	
PLATELETS	150-450 (10 ³ /UL)	28/11/91	185.00		276.00		228.00	
NA+	132-151 (MMOL/L)	28/11/91	143.00		140.00		143.00	
K+	3.6-5.2 (MMOL/L)	28/11/91	4.21		4.14		3.06	<<
CL-	97-108 (MMOL/L)	28/11/91	97.00		94.00	<	98.00	
Ca++	2.2-2.65 (MMOL/L)	28/11/91	2.45		2.00	<	2.27	
PO4--	2.5-5 (NG/DL)	28/11/91	5.34	>	10.20	>>	5.60	>
SGOT	5-15 (U/L)	28/11/91	71.00	>>	62.00	>>	50.00	>>
SGPT	5-19 (U/L)	28/11/91	50.00	>>	42.00	>>	44.00	>>
GAMMA GT	5-18 (U/L)	28/11/91	733.00	>>	752.00	>>	617.00	>>
LDH	120-240 (U/L)	28/11/91	270.00	>	301.00	>	210.00	>
ALK. PHOSPH.	65-175 (U/L)	28/11/91	219.00	>	250.00	>	201.00	>
GLUCOSE	50-100 (MG/DL)	28/11/91	73.00		88.00		121.00	>
CREATININE	0.5-0.9 (MG/DL)	28/11/91	0.86		1.04	>	0.79	
URIC ACID	2.5-6 (MG/DL)	28/11/91	8.60	>>	8.30	>>	8.40	>>
TOT. BILIRUBIN	0.2-1 (MG/DL)	28/11/91	0.69		0.72		0.85	
TOT. PROTEINS	6-8.5 (G/DL)	28/11/91	8.80	>	8.90	>	7.50	
ALBUMINE	55-60 (X)	28/11/91	62.80	>	62.40	>	59.00	
TOT. CHOLEST.	120-220 (MG/DL)	28/11/91	415.00	>>	381.00	>>	362.00	>>
TRIGLYCERIDES	45-200 (MG/DL)	28/11/91	562.00	>>	405.00	>>	221.00	>
GLOBULINS ALPHA 1	1-5 (X)	28/11/91	2.50		1.90		2.30	
GLOBULINS ALPHA 2	5-10 (X)	28/11/91	9.90		7.20		10.30	>
GLOBULINS BETA	7-12 (X)	28/11/91	11.00		11.40		12.40	>
GLOBULINS GAMMA	11-20 (X)	28/11/91	13.00		17.10		16.10	>
TSH	0.3-3 (MU/L)	28/11/91	2.90					
T4	4.5-12 (NG/DL)	28/11/91	5.50					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 7/07 Patient: 533 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date			
			Day 21		Day 42	
			25/05/92		15/06/92	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	13-18 (G/DL)	28/11/91			13.50	
HT	40-54 (X)	28/11/91			46.30	
RBC	4.4-5.9 (10 ⁶ /UL)	28/11/91			4.82	
WBC	4-10.8 (10 ³ /UL)	28/11/91			11.75 >	
WBC: N	45-70 (X)	28/11/91			65.90	
WBC: L	25-45 (X)	28/11/91			27.90	
WBC: E	1-5 (X)	28/11/91			1.20	
WBC: M	1-9 (X)	28/11/91			2.30	
WBC: B	0-2 (X)	28/11/91			0.80	
PLATELETS	150-450 (10 ³ /UL)	28/11/91			257.00	
NA+	132-151 (MMOL/L)	28/11/91	144.00		145.00	
K+	3.6-5.2 (MMOL/L)	28/11/91	3.75		6.66 >>	
CL-	97-108 (MMOL/L)	28/11/91	98.00		97.00	
Ca++	2.2-2.65 (MMOL/L)	28/11/91	2.49		2.02 <	
PO4--	2.5-5 (MG/DL)	28/11/91	5.90 >>		19.30 >>	
SGOT	5-19 (U/L)	28/11/91	9.00		12.00	
SGPT	5-23 (U/L)	28/11/91	10.00		14.00	
GAMMA GT	5-28 (U/L)	28/11/91	22.00		28.00	
LDH	120-240 (U/L)	28/11/91	287.00 >		378.00 >	
ALK. PHOSPH.	65-175 (U/L)	28/11/91	125.00		144.00	
GLUCOSE	50-100 (MG/DL)	28/11/91	104.00 >		104.00 >	
BUN	10-50 (MG/DL)	28/11/91				
UREA	()	28/11/91				
CREATININE	0.6-1.1 (MG/DL)	28/11/91	0.82		1.27 >	
URIC ACID	3.5-7 (MG/DL)	28/11/91	5.60		5.20	
TOT BILIRUBIN	0.2-1 (MG/DL)	28/11/91	0.61		0.41	
DIR BILIRUBIN	0-0.3 (MG/DL)	28/11/91				
TOT. PROTEINS	6-8.5 (G/DL)	28/11/91	7.90		8.10	
ALBUMINE	55-60 (X)	28/11/91	60.10 >		63.40 >	
TOT. CHOLEST.	120-220 (MG/DL)	28/11/91	344.00 >>		364.00 >>	
TRIGLYCERIDES	45-200 (MG/DL)	28/11/91	360.00 >>		551.00 >>	
GLOBULINS ALPHA 1	1-5 (X)	28/11/91	3.60		4.80	
GLOBULINS ALPHA 2	5-10 (X)	28/11/91	12.80 >		11.40 >	
GLOBULINS BETA	7-12 (X)	28/11/91	9.40		6.00 <	
GLOBULINS GAMMA	11-20 (X)	28/11/91	14.10		14.40	
TSH	0.3-3 (MU/L)	28/11/91				
T4	4.5-12 (NG/DL)	28/11/91				

1856

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 7/07 Patient: 534 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/05/92		05/06/92		24/06/92	
			value	(é)	value	(é)	value	(é)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	28/11/91	14.10		14.20		13.60	
HT	37-54 (X)	28/11/91	47.90		49.80		48.70	
RBC	3.8-5.2 (10 ⁶ /UL)	28/11/91	4.92		5.23 >		5.11	
HBC	4-10.8 (10 ³ /UL)	28/11/91	5.20		5.07		5.30	
HBC: N	45-70 (X)	28/11/91	64.20		70.10 >		65.70	
HBC: L	25-45 (X)	28/11/91	30.90		23.80 <		28.40	
HBC: E	1-5 (X)	28/11/91	0.30	<	0.40 <		0.40 <	
HBC: M	1-9 (X)	28/11/91	2.20		3.10		3.00	
HBC: B	0-2 (X)	28/11/91	0.90		1.00		1.10	
PLATELETS	150-450 (10 ³ /UL)	28/11/91	181.00		216.00		187.00	
NA+	132-151 (MMOL/L)	28/11/91	143.00		140.00		145.00	
K+	3.6-5.2 (MMOL/L)	28/11/91	7.67 >>		4.95		4.44	
CL-	97-108 (MMOL/L)	28/11/91	94.00 <		98.00		98.00	
Ca++	2.2-2.65 (MMOL/L)	28/11/91	2.16 <		2.26		2.41	
PO4--	2.5-5 (MG/DL)	28/11/91	21.70 >>		3.90		6.20 >>	
SGOT	5-15 (U/L)	28/11/91	8.00		11.00		10.00	
SGPT	5-19 (U/L)	28/11/91	9.00		10.00		9.00	
GAMMA GT	5-18 (U/L)	28/11/91	20.00 >		18.00		21.00 >	
LDH	120-240 (U/L)	28/11/91	207.00		229.00		221.00	
ALK. PHOSPH.	65-175 (U/L)	28/11/91	89.00		74.00		79.00	
GLUCOSE	50-100 (MG/DL)	28/11/91	101.00 >				92.00	
CREATININE	0.5-0.9 (MG/DL)	28/11/91	1.11 >		0.75		0.76	
URIC ACID	2.5-6 (MG/DL)	28/11/91	3.70		3.90		3.50	
TOT BILIRUBIN	0.2-1 (MG/DL)	28/11/91	0.56		0.39		0.27	
TOT. PROTEINS	6-8.5 (G/DL)	28/11/91	7.80		7.20		7.30	
ALBUMINE	55-60 (X)	28/11/91	70.00 >		68.00 >		68.00 >	
TOT. CHOLEST.	120-220 (MG/DL)	28/11/91	246.00 >		226.00 >		208.00	
TRIGLYCERIDES	45-200 (MG/DL)	28/11/91	487.00 >>		44.00 <		415.00 >>	
GLOBULINS ALPHA 1	1-5 (X)	28/11/91	1.90		2.30		1.60	
GLOBULINS ALPHA 2	5-10 (X)	28/11/91	7.00		8.00		7.10	
GLOBULINS BETA	7-12 (X)	28/11/91	8.70		8.60		8.70	
GLOBULINS GAMMA	11-20 (X)	28/11/91	12.40		13.10		14.60	
TSH	0.3-3 (MU/L)	28/11/91	2.80					
T4	4.5-12 (NG/DL)	28/11/91	7.80					

1857

(é) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 211 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			07/05/91
			value (†)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	14/02/91	14.30
HT	37-47 (%)	14/02/91	40.60
RBC	4.2-5 (10 ⁶ /UL)	14/02/91	4.97
WBC	4-9 (10 ³ /UL)	14/02/91	8.42
WBC: N	40-74 (%)	14/02/91	58.50
WBC: L	19-48 (%)	14/02/91	34.40
WBC: E	0-7 (%)	14/02/91	1.20
WBC: M	3.4-9 (%)	14/02/91	5.40
WBC: B	0-1.5 (%)	14/02/91	0.50
PLATELETS	130-400 (10 ³ /UL)	14/02/91	253.00
NA+	138-150 (MEQ/L)	14/02/91	139.00
K+	3.5-5 (MEQ/L)	14/02/91	4.50
CL-	98-110 (MEQ/L)	14/02/91	101.00
Ca++	8.5-10.5 (MG/DL)	14/02/91	9.50
PO4--	2.5-4.5 (MG/DL)	14/02/91	3.90
SGOT	5-40 (U/L)	14/02/91	15.00
SGPT	5-40 (U/L)	14/02/91	14.00
GAMMA GT	6-28 (U/L)	14/02/91	14.00
LDH	240-450 (U/L)	14/02/91	159.00 <
ALK. PHOSPH.	80-300 (U/L)	14/02/91	94.00
GLUCOSE	65-110 (MG/DL)	14/02/91	78.00
BUN	10-20 (MG/DL)	14/02/91	16.00
CREATININE	0.6-1.2 (MG/DL)	14/02/91	1.10
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	4.80
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	0.30
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.10
TOT. PROTEINS	6-8 (G/DL)	14/02/91	7.10
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	4.50
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	214.00
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	94.00
GLOBULINS ALPHA 1	1.5-5 (%)	14/02/91	1.34 <
GLOBULINS ALPHA 2	7.4-11 (%)	14/02/91	9.62
GLOBULINS BETA	9-14.1 (%)	14/02/91	14.99 >
GLOBULINS GAMMA	13-20.1 (%)	14/02/91	16.67
TSH	0.1-5 (UU/ML)	14/02/91	6.40 >>
T4	4.5-12.5 (UG/100ML)	14/02/91	11.60

1858

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 212 Treatment: Placebo Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			10/09/91		05/10/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	14/02/91	13.70			
HT	37-47 (X)	14/02/91	41.00			
RBC	4.2-5 (10-6/UL)	14/02/91	4.52			
WBC	4-9 (10-3/UL)	14/02/91	5.60			
WBC: N	40-74 (X)	14/02/91	64.50			
WBC: L	19-48 (X)	14/02/91	25.70			
WBC: E	0-7 (X)	14/02/91	1.70			
WBC: M	3.4-9 (X)	14/02/91	7.00			
WBC: B	0-1.5 (X)	14/02/91	1.10			
PLATELETS	130-400 (10-3/UL)	14/02/91	215.00			
NA+	138-150 (MEQ/L)	14/02/91	146.00			
K+	3.5-5 (MEQ/L)	14/02/91	4.80			
CL-	98-110 (MEQ/L)	14/02/91	102.00			
Ca++	8.5-10.5 (MG/DL)	14/02/91	8.80			
PO4--	2.5-4.5 (MG/DL)	14/02/91	3.80			
SGOT	5-40 (U/L)	14/02/91	16.00			
SGPT	5-40 (U/L)	14/02/91	14.00			
GAMMA GT	6-28 (U/L)	14/02/91	14.00			
LDH	240-450 (U/L)	14/02/91	227.00	<		
ALK. PHOSPH.	80-300 (U/L)	14/02/91	145.00			
GLUCOSE	65-110 (MG/DL)	14/02/91	74.00			
BUN	10-20 (MG/DL)	14/02/91	16.00			
CREATININE	0.6-1.2 (MG/DL)	14/02/91	1.00			
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	3.30			
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	0.55			
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.19			
TOT. PROTEINS	6-8 (G/DL)	14/02/91	6.00			
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	4.40			
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	252.00	>		
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	123.00			
GLOBULINS ALPHA 1	1.5-5 (X)	14/02/91	2.41			
GLOBULINS ALPHA 2	7.4-11 (X)	14/02/91	11.13	>		
GLOBULINS BETA	9-14.1 (X)	14/02/91	13.58			
GLOBULINS GAMMA	13-20.1 (X)	14/02/91	12.07	<		
TSH	0.1-5 (U/ML)	14/02/91			6.00 >>	
T4	4.5-12.5 (UG/100ML)	14/02/91			11.20	

1859

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 219 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date	
			Screen	
			18/11/91	
			value	(*)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	14/02/91	13.90	<
HT	42-52 (%)	14/02/91	41.10	<
RBC	4.6-5.6 (10 ⁶ /UL)	14/02/91	4.54	<
WBC	4-9 (10 ³ /UL)	14/02/91	8.14	
WBC: N	40-74 (%)	14/02/91	60.30	
WBC: L	19-48 (%)	14/02/91	29.20	
WBC: E	0-7 (%)	14/02/91	1.60	
WBC: M	3.4-9 (%)	14/02/91	8.20	
WBC: B	0-1.5 (%)	14/02/91	0.80	
PLATELETS	130-400 (10 ³ /UL)	14/02/91	286.00	
NA+	138-150 (MEQ/L)	14/02/91	143.00	
K+	3.5-5 (MEQ/L)	14/02/91	4.30	
CL-	98-110 (MEQ/L)	14/02/91	101.00	
Ca++	8.5-10.5 (MG/DL)	14/02/91	9.40	
PO4--	2.5-4.5 (MG/DL)	14/02/91	4.00	
SGOT	5-40 (U/L)	14/02/91	18.00	
SGPT	5-40 (U/L)	14/02/91	13.00	
GAMMA GT	6-28 (U/L)	14/02/91	12.00	
LDH	240-450 (U/L)	14/02/91	172.00	<
ALK. PHOSPH.	80-300 (U/L)	14/02/91	196.00	
GLUCOSE	65-110 (MG/DL)	14/02/91	84.00	
BUN	10-20 (MG/DL)	14/02/91	26.00	>
CREATININE	0.6-1.2 (MG/DL)	14/02/91	1.20	
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	5.60	
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	2.20	>>
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.46	>
TOT. PROTEINS	6-8 (G/DL)	14/02/91	7.60	
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	4.80	
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	249.00	>
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	102.00	
GLOBULINS ALPHA 1	1.5-5 (%)	14/02/91	2.53	
GLOBULINS ALPHA 2	7.4-11 (%)	14/02/91	7.88	
GLOBULINS BETA	9-14.1 (%)	14/02/91	14.90	>
GLOBULINS GAMMA	13-20.1 (%)	14/02/91	18.90	
TSH	0.1-5 (UU/ML)	14/02/91	0.20	
T4	4.5-12.5 (UG/100ML)	14/02/91	7.60	

1860

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 214 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			19/11/91		13/12/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	14/02/91	13.90		14.30	
HT	37-47 (X)	14/02/91	40.00		40.30	
RBC	4.2-5 (10 ⁶ /UL)	14/02/91	4.49		4.61	
WBC	4-9 (10 ³ /UL)	14/02/91	7.62		8.05	
WBC: N	40-74 (X)	14/02/91	70.60		63.90	
WBC: L	19-48 (X)	14/02/91	22.20		25.60	
WBC: E	0-7 (X)	14/02/91	1.80		3.30	
WBC: M	3.4-9 (X)	14/02/91	4.20		6.30	
WBC: B	0-1.5 (X)	14/02/91	1.20		0.90	
PLATELETS	130-400 (10 ³ /UL)	14/02/91	253.00		288.00	
NA+	138-150 (MEQ/L)	14/02/91	144.00		144.00	
K+	3.5-5 (MEQ/L)	14/02/91	4.40		4.40	
CL-	98-110 (MEQ/L)	14/02/91	101.00		101.00	
Ca++	8.5-10.5 (MG/DL)	14/02/91	9.90		10.10	
PO4--	2.5-4.5 (MG/DL)	14/02/91	2.90		4.00	
SGOT	5-40 (U/L)	14/02/91	12.00		18.00	
SGPT	5-40 (U/L)	14/02/91	13.00		20.00	
GAMMA GT	6-28 (U/L)	14/02/91	10.00		13.00	
LDH	240-450 (U/L)	14/02/91	141.00	<	175.00	
ALK. PHOSPH.	80-300 (U/L)	14/02/91	247.00		259.00	
GLUCOSE	65-110 (MG/DL)	14/02/91	84.00		87.00	
BUN	10-20 (MG/DL)	14/02/91	17.00		13.00	
CREATININE	0.6-1.2 (MG/DL)	14/02/91	1.00		0.90	
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	4.20		4.30	
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	0.57		0.38	
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.21		0.24	
TOT. PROTEINS	6-8 (G/DL)	14/02/91	7.30		7.70	
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	4.60		4.70	
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	168.00		209.00	
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	136.00		266.00	
GLOBULINS ALPHA 1	1.5-5 (X)	14/02/91	2.11		2.80	
GLOBULINS ALPHA 2	7.4-11 (X)	14/02/91	9.49		7.82	
GLOBULINS BETA	9-14.1 (X)	14/02/91	13.64		15.95	
GLOBULINS GAMMA	13-20.1 (X)	14/02/91	17.58		17.76	
TSH	0.1-5 (UU/ML)	14/02/91	2.10			
T4	4.5-12.5 (UG/100ML)	14/02/91	11.40			

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1861

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 215 Treatment: Placebo Sex: Female

			Visit number / Laboratory date
			Day 42
			31/03/92
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	14/02/91	15.40
HT	37-47 (%)	14/02/91	46.50
RBC	4.2-5 (10 ⁶ /UL)	14/02/91	4.96
WBC	4-9 (10 ³ /UL)	14/02/91	4.79
WBC: N	40-74 (%)	14/02/91	56.10
WBC: L	19-48 (%)	14/02/91	37.50
WBC: E	0-7 (%)	14/02/91	0.20
WBC: M	3.4-9 (%)	14/02/91	5.50
WBC: B	0-1.5 (%)	14/02/91	0.70
PLATELETS	130-400 (10 ³ /UL)	14/02/91	274.00
NA+	138-150 (MEQ/L)	14/02/91	142.00
K+	3.5-5 (MEQ/L)	14/02/91	4.10
CL-	98-110 (MEQ/L)	14/02/91	99.00
Ca++	8.5-10.5 (MG/DL)	14/02/91	9.70
PO4--	2.5-4.5 (MG/DL)	14/02/91	4.30
SGOT	5-40 (U/L)	14/02/91	10.00
SGPT	5-40 (U/L)	14/02/91	9.00
GAMMA GT	6-28 (U/L)	14/02/91	14.00
LDH	240-450 (U/L)	14/02/91	144.00 <
ALK. PHOSPH.	80-300 (U/L)	14/02/91	173.00
GLUCOSE	65-110 (MG/DL)	14/02/91	75.00
BUN	10-20 (MG/DL)	14/02/91	18.00
CREATININE	0.6-1.2 (MG/DL)	14/02/91	0.90
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	3.00
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	0.79
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.21
TOT. PROTEINS	6-8 (G/DL)	14/02/91	7.80
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	4.90
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	220.00
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	71.00

1862

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 216 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/03/92		14/04/92		05/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	14/02/91	16.50		16.40			
HT	42-52 (%)	14/02/91	49.70		50.90			
RBC	4.6-5.6 (10 ⁶ /UL)	14/02/91	5.36		5.49			
HBC	4-9 (10 ³ /UL)	14/02/91	7.20		10.55	>		
HBC: N	40-74 (%)	14/02/91	55.90		61.50			
HBC: L	19-48 (%)	14/02/91	34.70		29.50			
HBC: E	0-7 (%)	14/02/91	3.10		2.10			
HBC: N	3.4-9 (%)	14/02/91	5.00		5.90			
HBC: B	0-1.5 (%)	14/02/91	1.30		1.00			
PLATELETS	130-400 (10 ³ /UL)	14/02/91	234.00		295.00			
NA+	138-150 (MEQ/L)	14/02/91	141.00		145.00		140.00	
K+	3.5-5 (MEQ/L)	14/02/91	4.50		4.20		4.50	
CL-	98-110 (MEQ/L)	14/02/91	100.00		97.00	<	102.00	
Ca++	8.5-10.5 (MG/DL)	14/02/91	9.80		10.20		9.40	
PO4--	2.5-4.5 (MG/DL)	14/02/91	3.30		3.70		3.30	
SGOT	5-40 (U/L)	14/02/91	19.00		14.00		26.00	
SGPT	5-40 (U/L)	14/02/91	35.00		34.00		28.00	
GAMMA GT	6-28 (U/L)	14/02/91	31.00	>	34.00	>		
LDH	240-450 (U/L)	14/02/91	119.00	<	125.00	<		
ALK. PHOSPH.	80-300 (U/L)	14/02/91	190.00		224.00		195.00	
GLUCOSE	65-110 (MG/DL)	14/02/91	96.00		95.00		84.00	
BUN	10-20 (MG/DL)	14/02/91	13.00		13.00		18.00	
CREATININE	0.6-1.2 (MG/DL)	14/02/91	1.00		1.00		1.10	
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	5.00		5.80		5.00	
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	0.34		0.74		0.65	
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.19		0.16		0.08	
TOT. PROTEINS	6-8 (G/DL)	14/02/91	7.20		7.80		7.90	
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	4.60		4.90		6.10	
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	311.00	>>	330.00	>>		
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	390.00	>>	455.00	>>		
GLOBULINS ALPHA 1	1.5-5 (%)	14/02/91			2.95		4.00	
GLOBULINS ALPHA 2	7.4-11 (%)	14/02/91			3.79	<<	10.00	
GLOBULINS BETA	9-14.1 (%)	14/02/91			16.07		12.00	
GLOBULINS GAMMA	13-20.1 (%)	14/02/91			16.09		13.00	
TSH	0.1-5 (U/ML)	14/02/91	1.20					
T4	4.5-12.5 (UG/100ML)	14/02/91	9.40					

1863

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 217 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			23/03/92		20/04/92	
			value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	14/02/91	15.70		15.40	
HT	37-47 (X)	14/02/91	47.60 >		45.80	
RBC	4.2-5 (10 ⁶ /UL)	14/02/91	4.77		4.69	
MBC	4-9 (10 ³ /UL)	14/02/91	6.95		6.23	
MBC: N	40-74 (X)	14/02/91	50.20		57.30	
MBC: L	19-48 (X)	14/02/91	40.50		33.40	
MBC: E	0-7 (X)	14/02/91	3.20		1.90	
MBC: M	3.4-9 (X)	14/02/91	5.20		6.80	
MBC: B	0-1.5 (X)	14/02/91	0.90		0.60	
PLATELETS	130-400 (10 ³ /UL)	14/02/91	171.00		161.00	
NA+	138-150 (MEQ/L)	14/02/91	142.00		144.00	
K+	3.5-5 (MEQ/L)	14/02/91	4.10		4.30	
CL-	98-110 (MEQ/L)	14/02/91	100.00		103.00	
Ca++	8.5-10.5 (MG/DL)	14/02/91	10.00		9.80	
PO4--	2.5-4.5 (MG/DL)	14/02/91	3.10		3.30	
SCOT	5-40 (U/L)	14/02/91	22.00		20.00	
SCFT	5-40 (U/L)	14/02/91	21.00		21.00	
GAMMA GT	6-28 (U/L)	14/02/91	47.00 >		40.00 >	
LDH	240-450 (U/L)	14/02/91	153.00 <		150.00 <	
ALK. PHOSPH.	80-300 (U/L)	14/02/91	186.00		174.00	
GLUCOSE	65-110 (MG/DL)	14/02/91	73.00		80.00	
BUN	10-20 (MG/DL)	14/02/91	13.00		14.00	
CREATININE	0.6-1.2 (MG/DL)	14/02/91	0.90		0.80	
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	2.80		3.20	
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	1.09 >		1.00	
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.34 >		0.28	
TSH	0.1-5 (UU/ML)	14/02/91	1.20			
T4	4.5-12.5 (UG/100ML)	14/02/91	11.30			

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(ϕ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 218 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Day 42
			21/05/92
			value (4)
Laboratory test	Range value	Range date	
NA+	135-148 (MEQ/L)	20/05/92	143.00
K+	3.5-5 (MEQ/L)	20/05/92	4.10
CL-	98-108 (MEQ/L)	20/05/92	104.00
Ca++	8.5-10.5 (MG/DL)	20/05/92	9.00
PO4--	2.5-4.5 (MG/DL)	20/05/92	3.90
SGOT	1-40 (U/L)	20/05/92	21.00
SGPT	1-40 (U/L)	20/05/92	16.00
GAMMA GT	1-18 (U/L)	20/05/92	8.00
LDH	360-460 (U/L)	20/05/92	118.00 <
ALK. PHOSPH.	70-210 (U/L)	20/05/92	114.00
GLUCOSE	50-100 (MG/DL)	20/05/92	89.00
BUN	7-25 (MG/DL)	20/05/92	18.00
CREATININE	0.7-1.3 (MG/DL)	20/05/92	0.90
URIC ACID	3-7 (MG/DL)	20/05/92	5.00
TOT BILIRUBIN	0.3-1.1 (MG/DL)	20/05/92	0.65
DIR BILIRUBIN	0.05-0.2 (MG/DL)	20/05/92	0.13
TOT. PROTEINS	6.5-8.4 (G/DL)	20/05/92	7.20
ALBUMINE	55-65 (%)	20/05/92	55.00
TOT. CHOLEST.	160-240 (MG/DL)	20/05/92	210.00
TRIGLYCERIDES	50-160 (MG/DL)	20/05/92	140.00
GLOBULINS ALPHA 1	2-5 (%)	20/05/92	3.00
GLOBULINS ALPHA 2	7-12 (%)	20/05/92	11.00
GLOBULINS BETA	8-14 (%)	20/05/92	12.00
GLOBULINS GAMMA	12-20 (%)	20/05/92	19.00

1865

(4) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 219 Treatment: Placebo Sex: Female

			Visit number / Laboratory date	
			Screen	
			08/04/92	
			value	(†)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	02/04/92	11.60	<
HT	37-47 (%)	02/04/92	35.60	<
RBC	4.2-5 (10 ⁶ /UL)	02/04/92	4.46	
WBC	4-9 (10 ³ /UL)	02/04/92	6.72	
WBC: N	40-74 (%)	02/04/92	54.20	
WBC: L	19-46 (%)	02/04/92	38.20	
WBC: E	0-7 (%)	02/04/92	1.00	
WBC: M	3.4-9 (%)	02/04/92	6.10	
WBC: B	0-1.5 (%)	02/04/92	0.50	
PLATELETS	130-400 (10 ³ /UL)	02/04/92	263.00	
NA+	138-150 (MEQ/L)	02/04/92	141.00	
K+	3.5-5 (MEQ/L)	02/04/92	4.40	
CL-	98-110 (MEQ/L)	02/04/92	106.00	
Ca++	8.5-10.5 (MG/DL)	02/04/92	9.40	
PO4--	2.5-4.5 (MG/DL)	02/04/92	5.20	>>
SGOT	5-40 (U/L)	02/04/92	19.00	
SGPT	5-40 (U/L)	02/04/92	12.00	
GAMMA GT	6-28 (U/L)	02/04/92	5.00	<
LDH	240-450 (U/L)	02/04/92	91.00	<
ALK. PHOSPH.	80-300 (U/L)	02/04/92	206.00	
GLUCOSE	65-110 (MG/DL)	02/04/92	98.00	
BUN	10-20 (MG/DL)	02/04/92	12.00	
CREATININE	0.6-1.2 (MG/DL)	02/04/92	0.80	
URIC ACID	2.5-7.5 (MG/DL)	02/04/92	4.10	
TOT BILIRUBIN	0.1-1 (MG/DL)	02/04/92	0.29	
DIR BILIRUBIN	0.1-0.3 (MG/DL)	02/04/92	0.15	
TOT. PROTEINS	6-8 (G/DL)	02/04/92	8.90	>
ALBUMINE	50-67 (%)	02/04/92	40.19	<
TOT. CHOLEST.	120-220 (MG/DL)	02/04/92	126.00	
TRIGLYCERIDES	60-170 (MG/DL)	02/04/92	128.00	
GLOBULINS ALPHA 1	1.5-5 (%)	02/04/92	2.83	
GLOBULINS ALPHA 2	7.4-11 (%)	02/04/92	10.11	
GLOBULINS BETA	9-14.1 (%)	02/04/92	13.07	
GLOBULINS GAMMA	13-20.1 (%)	02/04/92	33.80	>>
TSH	0.1-5 (UU/ML)	02/04/92	1.00	
T4	4.5-12.5 (UG/100ML)	02/04/92	5.70	

1866

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 220 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Day 21
			18/05/92
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	14/02/91	12.20
HT	37-47 (X)	14/02/91	37.70
RBC	4.2-5 (10 ⁶ /UL)	14/02/91	3.97 <
WBC	4-9 (10 ³ /UL)	14/02/91	3.60 <
WBC: N	40-74 (X)	14/02/91	40.40
WBC: L	19-48 (X)	14/02/91	49.50 >
WBC: E	0-7 (X)	14/02/91	1.00
WBC: M	3.4-9 (X)	14/02/91	8.40
WBC: B	0-1.5 (X)	14/02/91	0.60
PLATELETS	130-400 (10 ³ /UL)	14/02/91	212.00
NA+	138-150 (MEQ/L)	14/02/91	136.00 <
K+	3.5-5 (MEQ/L)	14/02/91	4.00
CL-	98-110 (MEQ/L)	14/02/91	101.00
Ca++	8.5-10.5 (MG/DL)	14/02/91	9.70
PO4--	2.5-4.5 (MG/DL)	14/02/91	3.60
SGOT	5-40 (U/L)	14/02/91	16.00
SGPT	5-40 (U/L)	14/02/91	12.00
GAMMA GT	6-28 (U/L)	14/02/91	7.00
LDH	240-450 (U/L)	14/02/91	118.00 <
ALK. PHOSPH.	80-300 (U/L)	14/02/91	148.00
GLUCOSE	65-110 (MG/DL)	14/02/91	69.00
BUN	10-20 (MG/DL)	14/02/91	11.00
CREATININE	0.6-1.2 (MG/DL)	14/02/91	0.80
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	2.50
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	0.61
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.19
TOT. PROTEINS	6-8 (G/DL)	14/02/91	6.90
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	4.20
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	159.00
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	56.00 <
GLOBULINS ALPHA 1	1.5-5 (X)	14/02/91	2.00
GLOBULINS ALPHA 2	7.4-11 (X)	14/02/91	8.30
GLOBULINS BETA	9-14.1 (X)	14/02/91	8.80 <
GLOBULINS GAMMA	13-20.1 (X)	14/02/91	13.80

1867

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 221 Treatment: Inipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/04/92		19/05/92		09/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	20/04/92						
	11-16 (G/DL)	08/06/92	16.00					
HT	42-52 (X)	20/04/92						
	36-48 (X)	08/06/92	48.00					
RBC	4.6-5.6 (10 ⁶ /UL)	20/04/92						
	3.9-5.4 (10 ⁶ /UL)	08/06/92	5.30					
WBC	4-9 (10 ³ /UL)	20/04/92						
	4-8 (10 ³ /UL)	08/06/92	9.50 >					
WBC: N	40-74 (X)	20/04/92						
	50-80 (X)	08/06/92	58.00					
WBC: L	19-48 (X)	20/04/92						
	10-40 (X)	08/06/92	33.00					
WBC: E	0-7 (X)	20/04/92						
	0-4 (X)	08/06/92	3.00					
WBC: M	3.4-9 (X)	20/04/92						
	2-8 (X)	08/06/92	6.00					
WBC: B	0-1.5 (X)	20/04/92						
	0-2 (X)	08/06/92	0.00					
PLATELETS	130-400 (10 ³ /UL)	20/04/92						
	150-400 (10 ³ /UL)	08/06/92						
NA+	138-150 (MEQ/L)	20/04/92	140.00					
	135-148 (MEQ/L)	08/06/92	142.00					
K+	3.5-5 (MEQ/L)	20/04/92	5.00		4.40		4.40	
CL-	98-110 (MEQ/L)	20/04/92	96.00 <		104.00			
	98-108 (MEQ/L)	08/06/92						
Ca++	8.5-10.5 (MG/DL)	20/04/92	9.50		10.00		8.80	
PO4--	2.5-4.5 (MG/DL)	20/04/92	3.30		4.20		3.80	
SGOT	5-40 (U/L)	20/04/92	14.00		22.00			
	1-40 (U/L)	08/06/92	34.00					
SGPT	5-40 (U/L)	20/04/92	24.00		49.00 >			
	1-40 (U/L)	08/06/92	66.00 >					
GAMMA GT	6-28 (U/L)	20/04/92	29.00 >		38.00 >			
	1-18 (U/L)	08/06/92						
LDH	240-450 (U/L)	20/04/92	150.00 <		152.00 <			
	360-460 (U/L)	08/06/92						
ALK. PHOSPH.	80-300 (U/L)	20/04/92	219.00		222.00			
	70-210 (U/L)	08/06/92	242.00 >					
GLUCOSE	65-110 (MG/DL)	20/04/92	82.00		83.00		90.00	
	50-100 (MG/DL)	08/06/92	90.00					
BUN	10-20 (MG/DL)	20/04/92	14.00		19.00		14.00	
	7-25 (MG/DL)	08/06/92	14.00					
UREA	()	20/04/92						
	15-58 (MG/DL)	08/06/92						
CREATININE	0.6-1.2 (MG/DL)	20/04/92	0.90		1.10			
	0.7-1.3 (MG/DL)	08/06/92	0.90					
URIC ACID	2.5-7.5 (MG/DL)	20/04/92	5.30		6.60		6.10	
	3-7 (MG/DL)	08/06/92	6.10					
TOT BILIRUBIN	0.1-1 (MG/DL)	20/04/92	0.82		0.65		0.60	
	0.3-1.1 (MG/DL)	08/06/92	0.60					
DIR BILIRUBIN	0.1-0.3 (MG/DL)	20/04/92	0.23		0.19		0.10	
	0.05-0.2 (MG/DL)	08/06/92	0.10					
TOT. PROTEINS	6-8 (G/DL)	20/04/92	7.20		7.70		7.30	
	6.5-8.4 (G/DL)	08/06/92	7.30					
ALBUMINE	2.6-5.2 (G/DL)	20/04/92	4.50		4.60		55.00	
	55-65 (X)	08/06/92	55.00					
TOT. CHOLEST.	120-220 (MG/DL)	20/04/92	151.00		171.00			
	160-240 (MG/DL)	08/06/92						
TRIGLYCERIDES	60-170 (MG/DL)	20/04/92	160.00		111.00			
	50-160 (MG/DL)	08/06/92						
GLOBULINS ALPHA 1	1.5-5 (X)	20/04/92	3.56		2.43		4.00	
	2-5 (X)	08/06/92	4.00					
GLOBULINS ALPHA 2	7.4-11 (X)	20/04/92	9.58		8.03			

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1868

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 221 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/04/92		19/05/92		09/06/92	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
GLOBULINS ALPHA 2	7-12 (%)	08/06/92						
GLOBULINS BETA	9-14.1 (%)	20/04/92	13.93		14.55 >		12.00	
	8-14 (%)	08/06/92					10.00	
GLOBULINS GAMMA	13-20.1 (%)	20/04/92	19.50		18.15			
	12-20 (%)	08/06/92					19.00	
TSH	0.1-5 (UU/ML)	20/04/92	0.10					
	0.5-5 (UU/ML)	08/06/92						
T4	4.5-12.5 (UG/100ML)	20/04/92	11.50					
	4.5-11 (UG/DL)	08/06/92						

1869

(ϕ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 222 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/04/92		19/05/92		28/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/92	14.00		13.50			
	11-16 (G/DL)	27/06/92				13.00		
HT	37-47 (%)	01/04/92	41.50		39.10			
	36-48 (%)	27/06/92				40.00		
RBC	4.2-5 (10 ⁶ /UL)	01/04/92	4.47		4.19 <			
	3.9-5.4 (10 ⁶ /UL)	27/06/92				4.14		
WBC	4-9 (10 ³ /UL)	01/04/92	8.04		8.32			
	4-8 (10 ³ /UL)	27/06/92				7.50		
WBC: N	40-74 (%)	01/04/92	48.00					
	50-80 (%)	27/06/92				65.00		
WBC: L	19-48 (%)	01/04/92	45.00					
	10-40 (%)	27/06/92				31.00		
WBC: E	0-7 (%)	01/04/92	1.30					
	0-4 (%)	27/06/92				2.00		
WBC: M	3.4-9 (%)	01/04/92	5.00					
	2-8 (%)	27/06/92				2.00		
WBC: B	0-1.5 (%)	01/04/92	0.70					
	0-2 (%)	27/06/92				0.00		
PLATELETS	130-400 (10 ³ /UL)	01/04/92	257.00		211.00			
	150-400 (10 ³ /UL)	27/06/92				223.00		
NA+	138-150 (MEQ/L)	01/04/92	139.00		145.00			
	135-148 (MEQ/L)	27/06/92				140.00		
K+	3.5-5 (MEQ/L)	01/04/92	4.70		4.30			
	98-110 (MEQ/L)	01/04/92	102.00		107.00			
Ca++	8.5-10.5 (MG/DL)	01/04/92	9.60		9.10			
	2.5-4.5 (MG/DL)	01/04/92	3.60		3.20			
SGOT	5-40 (U/L)	01/04/92	17.00		15.00			
	1-40 (U/L)	27/06/92				31.00		
SGPT	5-40 (U/L)	01/04/92	12.00		14.00			
	1-40 (U/L)	27/06/92				19.00		
GAMMA GT	6-28 (U/L)	01/04/92	14.00		15.00			
	1-18 (U/L)	27/06/92				15.00		
LDH	240-450 (U/L)	01/04/92	193.00 <		191.00 <			
	360-460 (U/L)	27/06/92				300.00 <		
ALK. PHOSPH.	80-300 (U/L)	01/04/92	229.00		236.00			
	70-210 (U/L)	27/06/92				196.00		
GLUCOSE	65-110 (MG/DL)	01/04/92	86.00		80.00			
	50-100 (MG/DL)	27/06/92				117.00 >		
BUN	10-20 (MG/DL)	01/04/92	18.00		19.00			
	7-25 (MG/DL)	27/06/92				21.00		
CREATININE	0.6-1.2 (MG/DL)	01/04/92	1.10		1.10			
	0.7-1.3 (MG/DL)	27/06/92				1.10		
URIC ACID	2.5-7.5 (MG/DL)	01/04/92	4.80		5.10			
	3-7 (MG/DL)	27/06/92				4.60		
TOT. BILIRUBIN	0.1-1 (MG/DL)	01/04/92	0.42		0.30			
	0.3-1.1 (MG/DL)	27/06/92				0.54		
DIR. BILIRUBIN	0.1-0.3 (MG/DL)	01/04/92	0.23		0.14			
	0.05-0.2 (MG/DL)	27/06/92				0.10		
TOT. PROTEINS	6-8 (G/DL)	01/04/92	7.10		6.90			
	6.5-8.4 (G/DL)	27/06/92				7.30		
ALBUMINE	2.6-5.2 (G/DL)	01/04/92	4.40		4.30			
	55-65 (%)	27/06/92				60.00		
TOT. CHOLEST.	120-220 (MG/DL)	01/04/92	247.00 >		254.00 >			
	160-240 (MG/DL)	27/06/92				225.00		
TRIGLYCERIDES	60-170 (MG/DL)	01/04/92	152.00		275.00 >>			
	50-160 (MG/DL)	27/06/92				175.00 >		
GLOBULINS ALPHA 1	1.5-5 (%)	01/04/92	3.14		2.88			
	2-5 (%)	27/06/92				5.00		
GLOBULINS ALPHA 2	7.4-11 (%)	01/04/92	12.11 >		10.96			
	7-12 (%)	27/06/92				9.00		
GLOBULINS BETA	9-14.1 (%)	01/04/92	13.61		13.98			
	8-14 (%)	27/06/92				12.00		

1870

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(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 222 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/04/92		19/05/92		28/06/92	
			value	(†)	value	(†)	value	(†)
Laboratory test	Range value	Range date						
GLOBULINS GAMMA	13-20.1 (%)	01/04/92	17.27		15.60			
	12-20 (%)	27/06/92				14.00		
TSH	0.1-5 (UU/ML)	01/04/92	3.50					
T4	4.5-12.5 (UG/100ML)	01/04/92	5.90					

1871

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 223 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Day 21
			01/06/92
			value (⊕)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	21/05/92	14.60
HT	37-47 (%)	21/05/92	46.00
RBC	4.2-5 (10 ⁶ /UL)	21/05/92	4.89
WBC	4-9 (10 ³ /UL)	21/05/92	7.57
WBC: N	40-74 (%)	21/05/92	51.40
WBC: L	19-48 (%)	21/05/92	40.00
WBC: E	0-7 (%)	21/05/92	2.30
WBC: M	3.4-9 (%)	21/05/92	5.00
WBC: B	0-1.5 (%)	21/05/92	1.30
PLATELETS	130-400 (10 ³ /UL)	21/05/92	315.00
NA+	138-150 (ME/L)	21/05/92	146.00
K+	3.5-5 (ME/L)	21/05/92	4.80
CL-	98-110 (ME/L)	21/05/92	101.00
Ca++	8.5-10.5 (MG/DL)	21/05/92	10.10
PO4--	2.5-4.5 (MG/DL)	21/05/92	3.50
SGOT	5-40 (U/L)	21/05/92	22.00
SGPT	5-40 (U/L)	21/05/92	15.00
GAMMA GT	6-28 (U/L)	21/05/92	20.00
LDH	240-450 (U/L)	21/05/92	140.00 <
ALK. PHOSPH.	80-300 (U/L)	21/05/92	189.00
GLUCOSE	65-110 (MG/DL)	21/05/92	89.00
BUN	10-20 (MG/DL)	21/05/92	12.00
CREATININE	0.6-1.2 (MG/DL)	21/05/92	1.00
URIC ACID	2.5-7.5 (MG/DL)	21/05/92	5.40
TOT BILIRUBIN	0.1-1 (MG/DL)	21/05/92	0.84
DIR BILIRUBIN	0.1-0.3 (MG/DL)	21/05/92	0.28
TOT. PROTEINS	6-8 (G/DL)	21/05/92	7.30
ALBUMINE	2.6-5.2 (G/DL)	21/05/92	4.40
TOT. CHOLEST.	160-240 (MG/DL)	21/05/92	204.00
TRIGLYCERIDES	60-170 (MG/DL)	21/05/92	164.00
GLOBULINS ALPHA 1	1.5-5 (%)	21/05/92	3.10
GLOBULINS ALPHA 2	7.4-11 (%)	21/05/92	9.80
GLOBULINS BETA	9-14.1 (%)	21/05/92	12.90
GLOBULINS GAMMA	13-20.1 (%)	21/05/92	12.60 <

1872

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 224 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/08/92		28/09/92		19/10/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	21/05/92	11.00		12.00		11.80	
HT	36-48 (X)	21/05/92	34.00	<	37.00		35.00	<
RBC	3.9-5.4 (10~6/UL)	21/05/92	4.08		4.40		4.10	
WBC	4-8 (10~3/UL)	21/05/92	8.70	>	7.40		8.80	>
WBC: N	50-80 (X)	21/05/92	59.00		52.00		55.00	
WBC: L	10-40 (X)	21/05/92	36.00		40.00		37.00	
WBC: E	0-4 (X)	21/05/92	2.00		5.00	>	6.00	>>
WBC: M	2-8 (X)	21/05/92	3.00		3.00		2.00	
WBC: B	0-2 (X)	21/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10~3/UL)	21/05/92	220.00		220.00		210.00	
NA+	135-148 (MEQ/L)	21/05/92	140.00		142.00		146.00	
K+	3.5-5 (MEQ/L)	21/05/92	3.80		3.70		4.30	
CL-	98-108 (MEQ/L)	21/05/92	102.00		101.00		104.00	
Ca++	8.5-10.5 (MG/DL)	21/05/92	9.40		9.30		9.10	
PO4--	2.5-4.5 (MG/DL)	21/05/92	3.20		2.90		3.10	
SGOT	1-40 (U/L)	21/05/92	30.00		27.00		20.00	
SGPT	1-40 (U/L)	21/05/92	19.00		16.00		14.00	
GAMMA GT	1-18 (U/L)	21/05/92	7.00		7.00		6.00	
LDH	360-460 (U/L)	21/05/92	252.00	<	232.00	<	281.00	<
ALK. PHOSPH.	70-210 (U/L)	21/05/92	125.00		163.00		111.00	
GLUCOSE	50-100 (MG/DL)	21/05/92	79.00		81.00		68.00	
BUN	7-25 (MG/DL)	21/05/92	14.00		16.00		18.00	
CREATININE	0.7-1.3 (MG/DL)	21/05/92	0.30	<	0.80		0.80	
URIC ACID	3-7 (MG/DL)	21/05/92	3.20		3.50		2.90	<
TOT BILIRUBIN	0.3-1.1 (MG/DL)	21/05/92	0.65		0.85		0.82	
DIR BILIRUBIN	0.05-0.2 (MG/DL)	21/05/92	0.10		0.16		0.16	
TOT. PROTEINS	6.5-8.4 (G/DL)	21/05/92	7.60		7.70		7.40	
ALBUMINE	55-65 (X)	21/05/92	55.00		55.00		54.00	<
TOT. CHOLEST.	160-240 (MG/DL)	21/05/92	166.00		158.00	<	151.00	<
TRIGLYCERIDES	50-160 (MG/DL)	21/05/92	54.00		65.00		70.00	
GLOBULINS ALPHA 1	2-5 (X)	21/05/92	3.00		3.00		4.00	
GLOBULINS ALPHA 2	7-12 (X)	21/05/92	10.00		9.00		10.00	
GLOBULINS BETA	8-14 (X)	21/05/92	11.00		11.00		11.00	
GLOBULINS GAMMA	12-20 (X)	21/05/92	20.00		22.00	>	21.00	>
TSH	0.5-5 (UU/ML)	21/05/92	2.30					
T4	4.5-11 (UG/100ML)	21/05/92	5.20					

1873

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 225 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/09/92		02/10/92		23/10/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	21/05/92	15.20		16.00		14.50	
HT	36-48 (%)	21/05/92	44.00		47.00		42.00	
RBC	3.9-5.4 (10 ⁶ /UL)	21/05/92	4.95		5.30		4.70	
WBC	4-8 (10 ³ /UL)	21/05/92	8.00		7.20		7.40	
WBC: N	50-80 (%)	21/05/92	58.00		61.00		52.00	
WBC: L	10-40 (%)	21/05/92	39.00		34.00		44.00 >	
WBC: E	0-4 (%)	21/05/92	1.00		1.00		1.00	
WBC: M	2-8 (%)	21/05/92	2.00		4.00		3.00	
WBC: B	0-2 (%)	21/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	21/05/92	220.00		205.00		185.00	
HA+	135-148 (MEQ/L)	21/05/92	140.00		138.00		140.00	
K+	3.5-5 (MEQ/L)	21/05/92	5.00		4.70		4.70	
CL-	98-108 (MEQ/L)	21/05/92	107.00		99.00		100.00	
Ca++	8.5-10.5 (MG/DL)	21/05/92	8.50		9.00		9.30	
PO4--	2.5-4.5 (MG/DL)	21/05/92	3.60		3.10		3.50	
SGOT	1-40 (U/L)	21/05/92	34.00		30.00		37.00	
SGPT	1-40 (U/L)	21/05/92	37.00		28.00		42.00 >	
GAMMA GT	1-18 (U/L)	21/05/92	13.00		12.00		11.00	
LDH	360-460 (U/L)	21/05/92	339.00 <		271.00 <		329.00 <	
ALK. PHOSPH.	70-210 (U/L)	21/05/92	237.00 >		225.00 >		202.00	
GLUCOSE	50-100 (MG/DL)	21/05/92	82.00		68.00		78.00	
BUN	7-25 (MG/DL)	21/05/92	18.00		16.00		16.00	
CREATININE	0.7-1.3 (MG/DL)	21/05/92	0.80		0.80		0.80	
URIC ACID	3-7 (MG/DL)	21/05/92	4.00		5.00		4.30	
TOT BILIRUBIN	0.3-1.1 (MG/DL)	21/05/92	1.51 >		1.89 >		1.49 >	
DIR BILIRUBIN	0.05-0.2 (MG/DL)	21/05/92	0.87 >>		1.11 >>		0.69 >>	
TOT. PROTEINS	6.5-8.4 (G/DL)	21/05/92	8.40					
ALBUMINE	55-65 (%)	21/05/92	59.00					
TOT. CHOLEST.	160-240 (MG/DL)	21/05/92	184.00					
TRIGLYCERIDES	50-160 (MG/DL)	21/05/92	75.00					
GLOBULINS ALPHA 1	2-5 (%)	21/05/92	5.00					
GLOBULINS ALPHA 2	7-12 (%)	21/05/92	9.00					
GLOBULINS BETA	8-14 (%)	21/05/92	12.00					
GLOBULINS GAMMA	12-20 (%)	21/05/92	15.00					
TSH	0.5-5 (UU/ML)	21/05/92	1.30					
T4	4.5-11 (UG/100ML)	21/05/92	9.00					

1874

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 226 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/09/92		14/10/92		04/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	14/09/92	15.40		15.10		14.90	
HT	42-52 (%)	14/09/92	45.30		43.20		44.30	
RBC	4.6-5.6 (10 ⁶ /UL)	14/09/92	4.83		4.72		4.90	
WBC	4-9 (10 ³ /UL)	14/09/92	5.53		6.10		7.53	
WBC: N	40-74 (%)	14/09/92	62.00		59.60		55.40	
WBC: L	19-48 (%)	14/09/92	30.00		30.10		35.20	
WBC: E	0-7 (%)	14/09/92	3.20		0.90		3.00	
WBC: M	3.4-9 (%)	14/09/92	3.60		8.80		6.10	
WBC: B	0-1.5 (%)	14/09/92	1.20		0.40		0.30	
PLATELETS	130-400 (10 ³ /UL)	14/09/92	210.00		227.00		273.00	
NA+	138-150 (MEQ/L)	14/09/92	145.00		142.00		146.00	
K+	3.5-5 (MEQ/L)	14/09/92	4.80		3.80		3.50	
CL-	98-110 (MEQ/L)	14/09/92	100.00		101.00			
Ca++	8.5-10.5 (MG/DL)	14/09/92	9.70		9.40		9.70	
PO4--	2.5-4.5 (MG/DL)	14/09/92	3.80		3.50			
SGOT	5-40 (U/L)	14/09/92	32.00		24.00		16.00	
SGPT	5-40 (U/L)	14/09/92	39.00		30.00		17.00	
GAMMA GT	6-28 (U/L)	14/09/92	10.00		11.00		10.00	
LDH	240-450 (U/L)	14/09/92			233.00	<		
ALK. PHOSPH.	80-300 (U/L)	14/09/92	102.00		123.00		197.00	
GLUCOSE	65-110 (MG/DL)	14/09/92	77.00		79.00		90.00	
BUN	10-20 (MG/DL)	14/09/92	20.00		14.00		12.00	
CREATININE	0.6-1.2 (MG/DL)	14/09/92	1.10		1.10		1.00	
URIC ACID	2.5-7.5 (MG/DL)	14/09/92	3.90		4.50		5.40	
TOT BILIRUBIN	0.1-1 (MG/DL)	14/09/92	1.33	>	1.14	>	0.43	
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/09/92	0.48	>	0.34	>	0.23	
TOT. PROTEINS	6-8 (G/DL)	03/11/92					7.80	
ALBUMINE	50-67 (%)	03/11/92					64.50	
TOT. CHOLEST.	120-220 (MG/DL)	03/11/92					159.00	
TRIGLYCERIDES	60-170 (MG/DL)	03/11/92					91.00	
GLOBULINS ALPHA 1	1.5-5 (%)	03/11/92					2.40	
GLOBULINS ALPHA 2	7.4-11 (%)	03/11/92					6.20	
GLOBULINS BETA	9-14.1 (%)	03/11/92					10.50	
GLOBULINS GAMMA	13-20.1 (%)	03/11/92					16.40	
TSH	0.1-5 (UU/ML)	14/09/92	0.90					
T4	4.5-12.5 (UG/100ML)	14/09/92	8.10					

1875

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 227 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/09/92		16/10/92		06/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	21/05/92	15.40		14.60		14.10	
HT	42-52 (%)	21/05/92	46.70		46.00		43.50	
RBC	4.6-5.6 (10 ⁶ /UL)	21/05/92	5.26		4.89		4.56 <	
WBC	4-9 (10 ³ /UL)	21/05/92	9.24 >		7.57		9.59 >	
WBC: N	40-74 (%)	21/05/92	45.00		51.40		45.10	
WBC: L	19-48 (%)	21/05/92	45.30		40.00		44.00	
WBC: E	0-7 (%)	21/05/92	1.50		2.30		3.60	
WBC: M	3.4-9 (%)	21/05/92	7.20		5.00		6.30	
WBC: B	0-1.5 (%)	21/05/92	1.00		1.30		1.00	
PLATELETS	130-400 (10 ³ /UL)	21/05/92	291.00		315.00		238.00	
NA+	138-150 (ME/L)	21/05/92	137.00 <		146.00		140.00	
K+	3.5-5 (ME/L)	21/05/92	4.00		4.80		4.90	
CL-	98-110 (ME/L)	21/05/92	94.00 <		101.00		106.00	
Ca++	8.5-10.5 (MG/DL)	21/05/92	9.90		10.10		9.60	
PO4--	2.5-4.5 (MG/DL)	21/05/92	3.10		3.10			
SGOT	5-40 (U/L)	21/05/92	9.00		22.00		32.00	
SGPT	5-40 (U/L)	21/05/92	12.00		15.00		28.00	
GAMMA GT	6-28 (U/L)	21/05/92	13.00		20.00		9.00	
LDH	240-450 (U/L)	21/05/92	117.00 <				241.00	
ALK. PHOSPH.	80-300 (U/L)	21/05/92	186.00		300.00		133.00	
GLUCOSE	65-110 (MG/DL)	21/05/92	87.00		89.00		89.00	
BUN	10-20 (MG/DL)	21/05/92	15.00		12.00		11.00	
CREATININE	0.6-1.2 (MG/DL)	21/05/92	1.10		1.00		0.90	
URIC ACID	2.5-7.5 (MG/DL)	21/05/92	6.00		5.40		3.90	
TOT BILIRUBIN	0.1-1 (MG/DL)	21/05/92	0.46		0.84		0.46	
DIR BILIRUBIN	0.1-0.3 (MG/DL)	21/05/92	0.17		0.28		0.20	
TOT. PROTEINS	6-8 (G/DL)	21/05/92	7.20		7.30		7.20	
ALBUMINE	2.6-5.2 (G/DL)	21/05/92	4.40		4.40		4.70	
TOT. CHOLEST.	160-240 (MG/DL)	21/05/92	215.00		244.00 >		211.00	
TRIGLYCERIDES	60-170 (MG/DL)	21/05/92	203.00 >		164.00		111.00	
GLOBULINS ALPHA 1	1.5-5 (%)	21/05/92	2.55		3.10		2.90	
GLOBULINS ALPHA 2	7.4-11 (%)	21/05/92	9.38		9.80		11.40 >	
GLOBULINS BETA	9-14.1 (%)	21/05/92	15.34 >		12.90		11.50	
GLOBULINS GAMMA	13-20.1 (%)	21/05/92	16.29		12.90 <		9.30 <	
TSH	0.1-5 (UU/ML)	21/05/92	1.30					
T4	4.5-12.5 (UG/100ML)	21/05/92	5.20					

1876

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 228 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			19/09/92
			value (⊕)
Laboratory test	Range value	Range date	
HB	14-18 (G/DL)	14/02/91	15.70
HT	42-52 (Z)	14/02/91	45.10
RBC	4.6-5.6 (10 ⁶ /UL)	14/02/91	5.03
WBC	4-9 (10 ³ /UL)	14/02/91	7.29
WBC: N	40-74 (Z)	14/02/91	64.10
WBC: L	19-48 (Z)	14/02/91	21.60
WBC: E	0-7 (Z)	14/02/91	4.40
WBC: M	3.4-9 (Z)	14/02/91	8.40
WBC: B	0-1.5 (Z)	14/02/91	1.50
PLATELETS	130-400 (10 ³ /UL)	14/02/91	280.00
NA+	138-150 (MEQ/L)	14/02/91	140.00
K+	3.5-5 (MEQ/L)	14/02/91	4.10
CL-	98-110 (MEQ/L)	14/02/91	103.00
Ca ⁺⁺	8.5-10.5 (MG/DL)	14/02/91	10.00
PO ₄ ⁻⁻	2.5-4.5 (MG/DL)	14/02/91	3.20
SGOT	5-40 (U/L)	14/02/91	23.00
SGPT	5-40 (U/L)	14/02/91	20.00
GAMMA GT	6-28 (U/L)	14/02/91	13.00
LDH	240-450 (U/L)	14/02/91	259.00
ALK. PROSPH.	80-300 (U/L)	14/02/91	171.00
GLUCOSE	65-110 (MG/DL)	14/02/91	82.00
BUN	10-20 (MG/DL)	14/02/91	17.00
CREATININE	0.6-1.2 (MG/DL)	14/02/91	1.30 >
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	5.30
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	1.32 >
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.37 >
TOT. PROTEINS	6-8 (G/DL)	14/02/91	8.10 >
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	4.90
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	221.00 >
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	73.00
GLOBULINS ALPHA 1	1.5-5 (Z)	14/02/91	1.70
GLOBULINS ALPHA 2	7.4-11 (Z)	14/02/91	7.00 <
GLOBULINS BETA	9-14.1 (Z)	14/02/91	10.10
GLOBULINS GAMMA	13-20.1 (Z)	14/02/91	19.50
TSH	0.1-5 (UU/ML)	14/02/91	0.60
T4	8-20 (PG/ML)	14/02/91	15.70

1877

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 229 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/09/92		21/10/92		11/11/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	23/09/92	13.90		15.60		13.50	
HT	37-47 (%)	23/09/92	41.90		46.60		43.00	
RBC	4.2-5 (10 ⁶ /UL)	23/09/92	4.54		5.33	>	4.82	
HBC	4-9 (10 ³ /UL)	23/09/92	7.35		6.71		6.90	
HBC: N	40-74 (%)	23/09/92	53.20				63.00	
HBC: L	19-48 (%)	23/09/92	37.40				28.60	
HBC: E	0-7 (%)	23/09/92	3.50				2.60	
HBC: H	3.4-9 (%)	23/09/92	5.40				5.20	
HBC: B	0-1.5 (%)	23/09/92	0.50				0.70	
PLATELETS	130-400 (10 ³ /UL)	23/09/92	279.00		179.00		287.00	
NA+	138-150 (MEQ/L)	23/09/92	140.00		143.00		138.00	
K+	3.5-5 (MEQ/L)	23/09/92	3.70		3.90		4.50	
CL-	98-110 (MEQ/L)	23/09/92	100.00		98.00		101.00	
Ca++	8.5-10.5 (MG/DL)	23/09/92	9.30		9.70		10.60 >	
PO4--	2.5-4.5 (MG/DL)	23/09/92	3.90		2.70		5.20 >>	
SGOT	5-40 (U/L)	23/09/92	21.00		17.00		23.00	
SGPT	5-40 (U/L)	23/09/92	33.00		16.00		10.00	
GAMMA GT	5-40 (U/L)	23/09/92	12.00		11.00		9.00	
LDH	6-28 (U/L)	23/09/92	271.00		196.00	<	177.00 <	
ALK. PHOSPH.	240-450 (U/L)	23/09/92	179.00				199.00	
GLUCOSE	80-300 (U/L)	23/09/92	111.00	>			112.00 >	
BUN	65-110 (MG/DL)	23/09/92	10.00		20.00		15.00	
CREATININE	10-20 (MG/DL)	23/09/92	0.80		0.90		1.10	
URIC ACID	0.6-1.2 (MG/DL)	23/09/92	5.00		4.70		4.70	
TOT BILIRUBIN	2.5-7.5 (MG/DL)	23/09/92	0.41		0.48		0.50	
DIR BILIRUBIN	0.1-1 (MG/DL)	23/09/92	0.16		0.17		0.00 <	
TOT. PROTEINS	6-8 (G/DL)	23/09/92	7.30		7.70			
ALBUMINE	2.6-5.2 (G/DL)	23/09/92	4.20		4.80			
TOT. CHOLEST.	50-67 (%)	10/11/92					58.50	
TRIGLYCERIDES	120-220 (MG/DL)	23/09/92	221.00	>	208.00		207.00	
GLOBULINS ALPHA 1	60-170 (MG/DL)	23/09/92	212.00	>	94.00		102.00	
GLOBULINS ALPHA 2	1.5-5 (%)	23/09/92	2.30		3.26		2.80	
GLOBULINS BETA	7.4-11 (%)	23/09/92	8.90		10.75		8.80	
GLOBULINS GAMMA	9-14.1 (%)	23/09/92	12.60		11.77		12.30	
TSH	13-20.1 (U/ML)	23/09/92	18.00		18.89		17.60	
T4	0.1-5 (UU/ML)	23/09/92	0.90					
T4	4.5-12.5 (UG/100ML)	23/09/92	7.00					

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(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 230 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			24/09/92
			value (†)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	21/05/92	14.00
HT	37-47 (%)	21/05/92	42.80
RBC	4.2-5 (10 ⁶ /UL)	21/05/92	4.74
WBC	4-9 (10 ³ /UL)	21/05/92	8.90
WBC: N	40-74 (%)	21/05/92	67.70
WBC: L	19-48 (%)	21/05/92	24.30
WBC: E	0-7 (%)	21/05/92	1.50
WBC: M	3-4-9 (%)	21/05/92	5.80
WBC: B	0-1.5 (%)	21/05/92	0.70
PLATELETS	130-400 (10 ³ /UL)	21/05/92	369.00
NA+	138-150 (ME/L)	21/05/92	146.00
K+	3.5-5 (ME/L)	21/05/92	4.30
CL-	98-110 (ME/L)	21/05/92	101.00
Ca++	8.5-10.5 (MG/DL)	21/05/92	9.90
PO4--	2.5-4.5 (MG/DL)	21/05/92	4.30
SGOT	5-40 (U/L)	21/05/92	18.00
SGPT	5-40 (U/L)	21/05/92	14.00
GAMMA GT	6-28 (U/L)	21/05/92	13.00
LDH	240-450 (U/L)	21/05/92	270.00
ALK. PHOSPH.	80-300 (U/L)	21/05/92	292.00
GLUCOSE	65-110 (MG/DL)	21/05/92	72.00
BUN	10-20 (MG/DL)	21/05/92	10.00
CREATININE	0.6-1.2 (MG/DL)	21/05/92	0.80
URIC ACID	2.5-7.5 (MG/DL)	21/05/92	4.70
TOT BILIRUBIN	0.1-1 (MG/DL)	21/05/92	0.67
DIR BILIRUBIN	0.1-0.3 (MG/DL)	21/05/92	0.20
TOT. PROTEINS	6-8 (G/DL)	21/05/92	7.60
ALBUMINE	2.6-5.2 (G/DL)	21/05/92	4.80
TOT. CHOLEST.	160-240 (MG/DL)	21/05/92	219.00
TRIGLYCERIDES	60-170 (MG/DL)	21/05/92	137.00
TSH	0.1-5 (UU/ML)	21/05/92	1.30
T4	4.5-12.5 (UG/100ML)	21/05/92	9.90

1879

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value and laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 231 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/09/92		21/10/92		11/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	14/02/91	15.00		14.40		14.40	
HT	42-52 (X)	14/02/91	44.20		42.60		43.30	
RBC	4.6-5.6 (10 ⁶ /UL)	14/02/91	4.95		4.58 <		4.60	
HBC	4-9 (10 ³ /UL)	14/02/91	7.75		5.41		12.25 >>	
HBC: N	40-74 (X)	14/02/91	59.60		57.50		59.80	
HBC: L	19-48 (X)	14/02/91	33.30		33.10		31.40	
HBC: E	0-7 (X)	14/02/91	1.70		1.60		1.40	
HBC: M	3.4-9 (X)	14/02/91	4.90		6.80		6.40	
HBC: B	0-1.5 (X)	14/02/91	0.50		0.90		1.00	
PLATELETS	130-400 (10 ³ /UL)	14/02/91	303.00		183.00		226.00	
NA+	138-150 (MEQ/L)	14/02/91	140.00		145.00		143.00	
K+	3.5-5 (MEQ/L)	14/02/91	4.50		3.90		4.20	
CL-	98-110 (MEQ/L)	14/02/91	99.00		101.00		103.00	
Ca++	8.5-10.5 (MG/DL)	14/02/91	9.80				8.60	
PO4--	2.5-4.5 (MG/DL)	14/02/91	3.40				3.10	
SGOT	5-40 (U/L)	14/02/91			24.00		19.00	
SGPT	5-40 (U/L)	14/02/91	40.00		34.00		18.00	
GAMMA GT	6-28 (U/L)	14/02/91	23.00		9.00		10.00	
LDH	240-450 (U/L)	14/02/91	318.00				242.00	
ALK. PHOSPH.	80-300 (U/L)	14/02/91	220.00		136.00		193.00	
GLUCOSE	65-110 (MG/DL)	14/02/91	93.00		67.00		71.00	
BUN	10-20 (MG/DL)	14/02/91	13.00		19.00		19.00	
CREATININE	0.6-1.2 (MG/DL)	14/02/91	1.00		1.10		1.00	
URIC ACID	2.5-7.5 (MG/DL)	14/02/91	4.50		3.40		5.70	
TOT BILIRUBIN	0.1-1 (MG/DL)	14/02/91	1.02 >		0.88		0.52	
DIR BILIRUBIN	0.1-0.3 (MG/DL)	14/02/91	0.34 >		0.28		0.19	
TOT. PROTEINS	6-8 (G/DL)	14/02/91	8.00		7.40		6.80	
ALBUMINE	2.6-5.2 (G/DL)	14/02/91	5.00		4.50		4.80	
TOT. CHOLEST.	120-220 (MG/DL)	14/02/91	201.00		207.00		181.00	
TRIGLYCERIDES	60-170 (MG/DL)	14/02/91	146.00		101.00		163.00	
GLOBULINS ALPHA 1	1.5-5 (X)	14/02/91	2.00				2.90	
GLOBULINS ALPHA 2	7.4-11 (X)	14/02/91	8.40				8.50	
GLOBULINS BETA	9-14.1 (X)	14/02/91	11.30				12.40	
GLOBULINS GAMMA	13-20.1 (X)	14/02/91	13.00				8.90 <<	
TSH	0.1-5 (UU/ML)	14/02/91	0.80					
T4	8-20 (PG/ML)	14/02/91	18.00					

1880

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8 Patient: 232 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/09/92		23/10/92		13/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	21/05/92	16.70	>	15.60		15.20	
HT	36-48 (%)	21/05/92	48.00		43.00		44.00	
RBC	3.9-5.4 (10 ⁶ /UL)	21/05/92	5.10		4.75		4.66	
WBC	4-8 (10 ³ /UL)	21/05/92	6.70		6.00		6.20	
WBC: N	50-80 (%)	21/05/92	65.00		64.00		62.00	
WBC: L	10-40 (%)	21/05/92	29.00		32.00		32.00	
WBC: E	0-4 (%)	21/05/92	2.00		1.00		2.00	
WBC: M	2-8 (%)	21/05/92	4.00		3.00		4.00	
WBC: B	0-2 (%)	21/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	21/05/92	177.00		180.00		170.00	
NA+	135-148 (MEQ/L)	21/05/92	143.00		140.00		146.00	
K+	3.5-5 (MEQ/L)	21/05/92	4.50		5.30	>	5.20	
CL-	98-108 (MEQ/L)	21/05/92	104.00		103.00		106.00	
Ca++	8.5-10.5 (MG/DL)	21/05/92	9.20		9.50		9.50	
PO4--	2.5-4.5 (MG/DL)	21/05/92	3.50		3.20		3.40	
SGOT	1-40 (U/L)	21/05/92	32.00		25.00		18.00	
SGPT	1-40 (U/L)	21/05/92	27.00		19.00		17.00	
GAMMA GT	1-18 (U/L)	21/05/92	15.00		8.00		8.00	
LDH	360-460 (U/L)	21/05/92	300.00	<	252.00	<	310.00	
ALK. PHOSPH.	70-210 (U/L)	21/05/92	161.00		184.00		154.00	
GLUCOSE	50-100 (MG/DL)	21/05/92	85.00		85.00		80.00	
BUN	7-25 (MG/DL)	21/05/92	16.00		22.00		46.00	
CREATININE	0.7-1.3 (MG/DL)	21/05/92	1.10		1.10		1.10	
URIC ACID	3-7 (MG/DL)	21/05/92	6.80		6.20		5.70	
TOT BILIRUBIN	0.3-1.1 (MG/DL)	21/05/92	1.27	>	0.69		0.73	
DIR BILIRUBIN	0.05-0.2 (MG/DL)	21/05/92	0.68	>>	0.11		0.13	
TOT. PROTEINS	6.5-8.4 (MG/DL)	21/05/92	7.90		8.00		7.60	
ALBUMINE	55-65 (%)	21/05/92	58.00		55.00		56.00	
TOT. CHOLEST.	160-240 (MG/DL)	21/05/92	278.00	>	230.00		234.00	
TRIGLYCERIDES	50-160 (MG/DL)	21/05/92	209.00	>>	145.00		201.00	
GLOBULINS ALPHA 1	2-5 (%)	21/05/92	4.00		4.00		4.00	
GLOBULINS ALPHA 2	7-12 (%)	21/05/92	8.00		10.00		11.00	
GLOBULINS BETA	8-14 (%)	21/05/92	13.00		10.00		10.00	
GLOBULINS GAMMA	12-20 (%)	21/05/92	17.00		21.00	>	19.00	
TSH	0.5-5 (UU/ML)	21/05/92	1.70					
T4	4.5-11 (UG/100ML)	21/05/92	11.00					

1881

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 233 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/09/92		28/10/92		18/11/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (g/dL)	21/05/92	11.70		12.00		11.90	
BT	36-48 (%)	21/05/92	35.00 <		36.00		35.00 <	
RBC	3.9-5.4 (10 ⁶ /UL)	21/05/92	4.02		4.02		4.02	
WBC	4-8 (10 ³ /UL)	21/05/92	5.30		5.50		8.50 >	
WBC: N	50-80 (%)	21/05/92	65.00		63.00		69.00	
WBC: L	10-40 (%)	21/05/92	32.00		31.00		27.00	
WBC: E	0-4 (%)	21/05/92	2.00		1.00		1.00	
WBC: M	2-8 (%)	21/05/92	1.00 <		5.00		3.00	
WBC: B	0-2 (%)	21/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /UL)	21/05/92	227.00		226.00		350.00	
NA+	135-148 (MEQ/L)	21/05/92	142.00		143.00		144.00	
K+	3.5-5 (MEQ/L)	21/05/92	4.80		5.50 >		3.70	
CL-	98-108 (MEQ/L)	21/05/92	103.00		96.00 <		102.00	
Ca++	8.5-10.5 (MG/DL)	21/05/92	9.10		9.20		9.50	
PO4--	2.5-4.5 (MG/DL)	21/05/92	3.20		2.90		3.40	
SGOT	1-40 (U/L)	21/05/92	22.00		20.00		32.00	
SGPT	1-40 (U/L)	21/05/92	13.00		13.00		21.00	
GAMMA GT	1-18 (U/L)	21/05/92	6.00		6.00		7.00	
LDH	360-460 (U/L)	21/05/92	300.00 <		261.00 <		252.00 <	
ALK. PHOSPH.	70-210 (U/L)	21/05/92	193.00		153.00		144.00	
GLUCOSE	50-100 (MG/DL)	21/05/92	84.00		90.00		90.00	
BUN	7-25 (MG/DL)	21/05/92	11.00		10.00		9.00	
CREATININE	0.7-1.3 (MG/DL)	21/05/92	0.80		0.60 <		0.70	
URIC ACID	3-7 (MG/DL)	21/05/92	4.30		4.00		2.80 <	
TOT BILIRUBIN	0.3-1.1 (MG/DL)	21/05/92	0.65		0.65		0.54	
DIR BILIRUBIN	0.05-0.2 (MG/DL)	21/05/92	0.11		0.11		0.10	
TOT. PROTEINS	6.5-8.4 (MG/DL)	21/05/92	7.30		7.70		7.90	
ALBUMINE	55-65 (%)	21/05/92	51.00 <		45.00 <		48.00 <	
TOT. CHOLEST.	160-240 (MG/DL)	21/05/92	170.00		216.00		196.00	
TRIGLYCERIDES	50-160 (MG/DL)	21/05/92	74.00		93.00		131.00	
GLOBULINS ALPHA 1	2-5 (%)	21/05/92	3.00		4.00		5.00	
GLOBULINS ALPHA 2	7-12 (%)	21/05/92	9.00		11.00		10.00	
GLOBULINS BETA	8-14 (%)	21/05/92	11.00		10.00		10.00	
GLOBULINS GAMMA	12-20 (%)	21/05/92	26.00 >		30.00 >>		27.00 >>	
TSH	0.5-5 (UU/ML)	21/05/92	0.80					
T4	4.5-11 (UG/100ML)	21/05/92	10.20					

1882

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8 Patient: 234 Treatment: Placebo Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			30/09/92	28/10/92
			value (†)	value (†)
Laboratory test	Range value	Range date		
HB	11-16 (G/DL)	21/05/92	13.50	13.70
HT	36-48 (X)	21/05/92	40.00	40.00
RBC	3.9-5.4 (10 ⁶ /UL)	21/05/92	4.36	4.42
WBC	4-8 (10 ³ /UL)	21/05/92	7.80	6.90
WBC: N	50-80 (%)	21/05/92	68.00	63.00
WBC: L	10-40 (%)	21/05/92	27.00	32.00
WBC: E	0-4 (%)	21/05/92	2.00	2.00
WBC: M	2-8 (%)	21/05/92	2.00	3.00
WBC: B	0-2 (%)	21/05/92	1.00	0.00
PLATELETS	150-400 (10 ³ /UL)	21/05/92	260.00	260.00
NA+	135-148 (MEQ/L)	21/05/92	142.00	140.00
K+	3.5-5 (MEQ/L)	21/05/92	4.70	5.30 >
CL-	98-108 (MEQ/L)	21/05/92	107.00	101.00
Ca++	8.5-10.5 (MG/DL)	21/05/92	8.90	9.10
PO4--	2.5-4.5 (MG/DL)	21/05/92	2.90	4.30
SGOT	1-40 (U/L)	21/05/92	28.00	38.00
SGPT	1-40 (U/L)	21/05/92	17.00	17.00
GAMMA GT	1-18 (U/L)	21/05/92	21.00 >	22.00 >
LDH	360-460 (U/L)	21/05/92	261.00 <	281.00 <
ALK. PHOSPH.	70-210 (U/L)	21/05/92	189.00	171.00
GLUCOSE	50-100 (MG/DL)	21/05/92	73.00	69.00
BUN	7-25 (MG/DL)	21/05/92	16.00	16.00
UREA	()	21/05/92		
CREATININE	0.7-1.3 (MG/DL)	21/05/92	1.00	1.10
URIC ACID	3-7 (MG/DL)	21/05/92	4.70	4.70
TOT BILIRUBIN	0.3-1.1 (MG/DL)	21/05/92	0.54	0.58
DIR BILIRUBIN	0.05-0.2 (MG/DL)	21/05/92	0.10	0.10
TOT. PROTEINS	6.5-8.4 (MG/DL)	21/05/92	8.10	8.00
ALBUMINE	55-65 (X)	21/05/92	58.00	59.00
TOT. CHOLEST.	160-240 (MG/DL)	21/05/92	235.00	260.00 >
TRIGLYCERIDES	50-160 (MG/DL)	21/05/92	155.00	222.00 >>
GLOBULINS ALPHA 1	2-5 (X)	21/05/92	4.00	4.00
GLOBULINS ALPHA 2	7-12 (X)	21/05/92	10.00	9.00
GLOBULINS BETA	8-14 (X)	21/05/92	11.00	10.00
GLOBULINS GAMMA	12-20 (X)	21/05/92	17.00	18.00
TSH	0.5-5 (UU/ML)	21/05/92	1.10	
T4	4.5-11 (UG/100ML)	21/05/92	7.30	

1883

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8/A Patient: 235 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/09/92		03/11/92		24/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92	15.50		14.00		15.00	
RBC	3500000-5600000 (/UL)	01/09/92						
HBC	4000-10000 (/UL)	01/09/92	4570000		4600000		4590000	
HBC: N	50-70 (%)	01/09/92	7100.00		6800.00		7600.00	
HBC: L	20-30 (%)	01/09/92	54.00	>>	30.00		37.00 >	
HBC: E	0-1 (%)	01/09/92	0.00		0.00		0.00	
HBC: M	0-1 (%)	01/09/92	2.00	>>	0.00		0.00	
HBC: B	0-1 (%)	01/09/92	0.00		0.00		0.00	
NA+	135-150 (MEQ/L)	01/09/92	145.00		140.00		140.00	
K+	3.6-5.5 (MEQ/L)	01/09/92	5.10		4.00		4.40	
CL-	98-115 (MEQ/L)	01/09/92	111.00					
PO4--	2-6.8 (MEQ/L)	01/09/92	3.20		3.60		4.90	
SGOT	5-24 (U/L)	01/09/92	20.00		18.00		18.00	
SGPT	5-22 (U/L)	01/09/92	22.00		24.00 >		21.00	
ALK. PHOSPH.	72-244 (MU/ML)	01/09/92	237.00		220.00		218.00	
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	0.92		0.98		0.97	
BUN	0.22-0.6 (MG/DL)	01/09/92	0.43		0.45		0.47	
CREATININE	0.5-0.9 (MG/DL)	01/09/92	0.80		0.86		0.82	
URIC ACID	2-6 (MG/DL)	01/09/92	5.00		5.20		4.80	
TOT. BILIRUBIN	0.25-1 (MG/DL)	01/09/92	0.57		0.70		0.68	
DIR. BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.16		0.20		0.17	
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92			7.00		7.20	
ALBUMINE	50-64 (%)	01/09/92	56.90		56.10		57.70	
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	241.00		248.00		237.00	
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	142.00		130.00		118.00	
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	3.00		3.90		4.70 >	
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	7.40		10.90 >		8.80	
GLOBULINS BETA	8-12 (%)	01/09/92	9.20		12.60 >		10.20	
GLOBULINS GAMMA	14-22 (%)	01/09/92	23.50 >		16.50		18.60	
TSH	0.35-7 (MU/ML)	01/09/92	2.20					
T4	5-10.6 (UG%)	01/09/92	9.10					

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(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8/A Patient: 236 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/09/92		03/11/92		24/11/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92	12.10		12.00		12.00	
RBC	3500000-5600000 (/UL)	01/09/92						
HBC	4000-10000 (/UL)	01/09/92	5990000 >	5400000	5900000 >			
HBC: N	50-70 (X)	01/09/92	9900.00	8800.00	8700.00			
HBC: L	20-30 (X)	01/09/92	68.00	65.00	74.00 >			
HBC: E	0-1 (X)	01/09/92	30.00	35.00 >	26.00			
HBC: H	0-1 (X)	01/09/92	0.00	0.00	0.00			
HBC: B	0-1 (X)	01/09/92	2.00 >>	0.00	0.00			
NA+	135-150 (MEQ/L)	01/09/92	0.00	0.00	0.00			
K+	3.6-5.5 (MEQ/L)	01/09/92	142.00	140.00	144.00			
CL-	98-115 (MEQ/L)	01/09/92	4.40	3.80	3.90			
PO4--	2-6.8 (MEQ/L)	01/09/92	110.00					
SGOT	5-24 (U/L)	01/09/92		3.00	3.60			
SGPT	5-24 (U/L)	01/09/92	12.00	17.00	13.20			
ALK. PHOSPH.	72-244 (MU/ML)	01/09/92	17.00	18.00	15.70			
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	124.00	117.00	177.00			
BUN	0.22-0.6 (MG/DL)	01/09/92	0.76	0.88	0.82			
CREATININE	0.5-0.9 (MG/DL)	01/09/92	0.25	0.27	0.31			
URIC ACID	2-6 (MG/DL)	01/09/92	0.80	0.84	0.78			
TOT. BILIRUBIN	0.25-1 (MG/DL)	01/09/92	5.00	4.40	4.00			
DIR BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.71	0.70	0.74			
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92	0.16	0.15	0.17			
ALBUMINE	50-64 (X)	01/09/92	7.40	7.30	7.20			
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	60.97	56.30	62.09			
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	201.00	210.00	198.00			
GLOBULINS ALPHA 1	2-4 (X)	01/09/92	112.00	110.00	96.00			
GLOBULINS ALPHA 2	6-10 (X)	01/09/92	3.90	3.70	3.70			
GLOBULINS BETA	8-12 (X)	01/09/92	8.09	9.90	6.40			
GLOBULINS GAMMA	14-22 (X)	01/09/92	14.09 >	11.60	10.80			
TSH	0.35-7 (MU/ML)	01/09/92	12.95 <	18.50	17.20			
T4	5-10.6 (UGX)	01/09/92	2.10					
			7.90					

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8/A Patient: 237 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/09/92		03/11/92		24/11/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92	14.40		14.00		14.80	
RBC	3500000-5600000 (/UL)	01/09/92	5000000		4800000		4880000	
HBC	4000-10000 (/UL)	01/09/92	5100.00		4600.00		5600.00	
HBC: N	50-70 (%)	01/09/92	56.00		74.00 >		57.00	
HBC: L	20-30 (%)	01/09/92	42.00 >>		26.00		40.00 >>	
HBC: E	0-1 (%)	01/09/92	0.00		0.00		0.00	
HBC: M	0-1 (%)	01/09/92	2.00 >>		0.00		3.00 >>	
HBC: B	0-1 (%)	01/09/92	0.00		0.00		0.00	
NA+	135-150 (NEQ/L)	01/09/92	142.00		143.00		144.00	
K+	3.6-5.5 (NEQ/L)	01/09/92	4.20		4.00		4.30	
PO4--	2-6.8 (NEQ/L)	01/09/92	3.40		3.90		4.00	
SGOT	5-24 (U/L)	01/09/92	20.00		28.20 >		22.00	
SGPT	5-22 (U/L)	01/09/92	29.00 >		32.50 >		29.00 >	
ALK. PHOSPH.	72-244 (MU/ML)	01/09/92	179.00		188.00		213.00	
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	0.86		0.90		0.90	
BUN	0.22-0.6 (MG/DL)	01/09/92	0.24		0.32		0.30	
CREATININE	0.5-0.9 (MG/DL)	01/09/92	0.70		0.76		0.69	
URIC ACID	2-6 (MG/DL)	01/09/92	4.00		4.80		4.40	
TOT BILIRUBIN	0.25-1 (MG/DL)	01/09/92	0.50		0.55		0.57	
DIR BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.15		0.20		0.12	
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92	7.60		7.00		7.70	
ALBUMINE	50-64 (G)	01/09/92	60.47		54.70		62.30	
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	314.00 >		298.00 >		288.00 >	
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	158.00		144.00		155.00	
GLOBULINS ALPHA 1	2-4 (G)	01/09/92	4.16 >		4.00		2.70	
GLOBULINS ALPHA 2	6-10 (G)	01/09/92	8.57		9.60		8.00	
GLOBULINS BETA	8-12 (G)	01/09/92	14.79 >		16.20 >>		11.60	
GLOBULINS GAMMA	14-22 (G)	01/09/92	12.01 <		15.50		15.40	
TSH	0.35-7 (MU/ML)	01/09/92	1.48					
T4	5-10.6 (UGX)	01/09/92	9.10					

1886

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8/A Patient: 238 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/09/92		03/11/92		24/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92	13.00		12.00	13.10		
RBC	3500000-5600000 (/UL)	01/09/92						
			3980000		3700000	4000000		
			6000.00		6600.00	6700.00		
WBC	4000-10000 (/UL)	01/09/92						
WBC: N	50-70 (%)	01/09/92	60.00		67.00	75.00 >		
WBC: L	20-30 (%)	01/09/92	38.00 >		33.00 >	25.00		
WBC: E	0-1 (%)	01/09/92	0.00		0.00	0.00		
WBC: M	0-1 (%)	01/09/92	2.00 >>		0.00	0.00		
WBC: B	0-1 (%)	01/09/92	0.00		0.00	0.00		
NA+	135-150 (MEQ/L)	01/09/92	144.00		144.00	140.00		
K+	3.6-5.5 (MEQ/L)	01/09/92	4.50		4.20	4.40		
CL-	98-115 (MEQ/L)	01/09/92	114.00					
PO4--	2-6.8 (MEQ/L)	01/09/92	3.70		3.90	3.90		
SGOT	5-24 (U/L)	01/09/92	19.00		18.00	13.00		
SGPT	5-22 (U/L)	01/09/92	21.00		21.00	15.00		
ALK. PHOSPH.	72-244 (MU/ML)	01/09/92	194.00		177.00	188.00		
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	0.94		0.95	0.95		
BUN	0.22-0.6 (MG/DL)	01/09/92	0.39		0.40	0.41		
CREATININE	0.5-0.9 (MG/DL)	01/09/92	0.90		0.92 >	0.82		
URIC ACID	2-6 (MG/DL)	01/09/92	6.00		6.30 >	5.50		
TOT. BILIRUBIN	0.25-1 (MG/DL)	01/09/92	0.75		0.76	0.79		
DIR. BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.18		0.16	0.20		
TOT. PROTEINS	6.5-8 (NG/DL)	01/09/92	6.30 <		6.50	7.00		
ALBUMINE	50-64 (%)	01/09/92	59.37		59.70	59.70		
TOT. CHOLEST.	130-250 (NG/DL)	01/09/92	168.00		176.00	176.00		
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	223.00 >		226.00 >>	165.00		
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	4.11 >		2.40	2.40		
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	8.72		7.50	7.50		
GLOBULINS BETA	8-12 (%)	01/09/92	17.00 >>		8.40	10.40		
GLOBULINS GAMMA	14-22 (%)	01/09/92	10.80 <		22.00	20.00		
TSH	0.35-7 (MU/ML)	01/09/92	0.78					
T4	5-10.6 (UGX)	01/09/92	8.50					

1887

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8/A Patient: 239 Treatment: Imipramine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			22/09/92		05/11/92		26/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92	13.50		13.00		13.20	
RBC	3500000-5600000 (/UL)	01/09/92						
			4450000		4400000		4550000	
			6500.00		6900.00		7300.00	
HBC	4000-10000 (/UL)	01/09/92						
HBC: N	50-70 (%)	01/09/92	66.00		76.00		75.00	
HBC: L	20-30 (%)	01/09/92	34.00	>	24.00		25.00	
HBC: E	0-1 (%)	01/09/92	0.00		0.00		0.00	
HBC: M	0-1 (%)	01/09/92	0.00		0.00		0.00	
HBC: B	0-1 (%)	01/09/92	0.00		0.00		0.00	
NA+	135-150 (MEQ/L)	01/09/92	138.00		144.00		143.00	
K+	3.6-5.5 (MEQ/L)	01/09/92	4.60		4.10		4.50	
PO4--	2-6.8 (MEQ/L)	01/09/92	3.90		6.00		6.00	
SGOT	5-24 (U/L)	01/09/92	12.00		11.00		12.00	
SGPT	5-22 (U/L)	01/09/92	16.00		16.00		15.00	
ALK. PHOSPH.	72-244 (MU/ML)	01/09/92	117.00		203.00		188.00	
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	0.98		0.94		0.90	
BUN	0.22-0.6 (MG/DL)	01/09/92	0.41		0.38		0.35	
CREATININE	0.5-0.9 (MG/DL)	01/09/92	0.76		0.73		0.70	
URIC ACID	2-6 (MG/DL)	01/09/92	4.00		4.00		3.50	
TOT BILIRUBIN	0.25-1 (MG/DL)	01/09/92	0.70		0.62		0.70	
DIR BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.12		0.13		0.14	
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92	6.90		7.10		6.80	
ALBUMINE	50-64 (%)	01/09/92	56.30		58.10		56.20	
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	213.00		198.00		196.00	
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	117.00		103.00		90.00	
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	3.70		4.70		4.50	
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	10.90	>	7.30		11.60	
GLOBULINS BETA	8-12 (%)	01/09/92	11.60		12.40		13.50	
GLOBULINS GAMMA	14-22 (%)	01/09/92	17.50		17.50		14.20	
TSH	0.35-7 (MU/ML)	01/09/92	1.90					
T4	5-10.6 (UGX)	01/09/92	7.40					

1888

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: B/A Patient: 240 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/09/92		05/11/92		26/11/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92	13.00		13.00		13.70	
RBC	3500000-5600000 (/UL)	01/09/92	4220000		4330000		4440000	
WBC	4000-10000 (/UL)	01/09/92	5700.00		4800.00		5400.00	
WBC: N	50-70 (%)	01/09/92	61.00		63.00		64.00	
WBC: L	20-30 (%)	01/09/92	36.00 >		35.00 >		36.00 >	
WBC: E	0-1 (%)	01/09/92	0.00		0.00		0.00	
WBC: M	0-1 (%)	01/09/92	0.00		2.00 >>		0.00	
WBC: B	0-1 (%)	01/09/92	0.00		0.00		0.00	
NA+	135-150 (NEQ/L)	01/09/92	143.00		138.00		139.00	
K+	3.6-5.5 (NEQ/L)	01/09/92	3.60		4.30		4.30	
PO4--	2-6.8 (NEQ/L)	01/09/92	4.50		5.30		5.00	
SGOT	5-24 (U/L)	01/09/92	16.00		14.00		12.00	
SGPT	5-22 (U/L)	01/09/92	19.00		17.00		11.00	
ALK. PHOSPH.	72-244 (NU/ML)	01/09/92	123.00		177.00		155.00	
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	0.78		0.84		0.87	
BUN	0.22-0.6 (MG/DL)	01/09/92	0.26		0.28		0.32	
CREATININE	0.5-0.9 (MG/DL)	01/09/92	0.71		0.76		0.68	
URIC ACID	2-6 (MG/DL)	01/09/92	4.50		5.00		4.70	
TOT BILIRUBIN	0.25-1 (MG/DL)	01/09/92	0.58		0.63		0.65	
DIR BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.10		0.14		0.15	
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92	6.60		7.10		6.90	
ALBUMINE	50-64 (%)	01/09/92	63.30		54.10		53.10	
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	178.00		194.00		190.00	
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	110.00		116.00		94.00	
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	3.70		3.90		3.70	
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	8.80		10.30 >		9.90	
GLOBULINS BETA	8-12 (%)	01/09/92	9.40		10.90		12.30 >	
GLOBULINS GAMMA	14-22 (%)	01/09/92	14.80		20.80		21.00	
TSH	0.35-7 (MU/ML)	01/09/92	0.95					
T4	5-10.6 (UGX)	01/09/92	8.50					

1889

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 8/A Patient: 553 Treatment: Placebo Sex: Female

Laboratory test			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/09/92		05/11/92		26/11/92	
			value	(€)	value	(€)	value	(€)
Range value	Range date							
HB	12-18 (G/DL)	01/09/92	12.80		13.00		13.60	
RBC	3500000-5600000 (/UL)	01/09/92	4300000		4410000		4620000	
NBC	4000-10000 (/UL)	01/09/92	4200.00		4600.00		5400.00	
NBC: N	50-70 (%)	01/09/92	67.00		76.00 >		76.00 >	
NBC: L	20-30 (%)	01/09/92	33.00 >		24.00		24.00	
NBC: E	0-1 (%)	01/09/92	0.00		0.00		0.00	
NBC: M	0-1 (%)	01/09/92	0.00		0.00		0.00	
NBC: B	0-1 (%)	01/09/92	0.00		0.00		0.00	
NA+	135-150 (NEQ/L)	01/09/92	144.00		140.00		142.00	
K+	3.6-5.5 (NEQ/L)	01/09/92	4.10		4.30		4.40	
PO4--	2-6.8 (MEQ/L)	01/09/92	4.20		3.80		4.70	
SGOT	5-24 (U/L)	01/09/92	15.70		14.00		13.30	
SGPT	5-22 (U/L)	01/09/92	18.20		16.00		17.10	
ALK. PHOSPH.	72-244 (MU/ML)	01/09/92	177.30		172.30		177.00	
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	1.16 >		1.17 >		1.19 >	
BUN	0.22-0.6 (MG/DL)	01/09/92	0.34		0.38		0.38	
CREATININE	0.5-0.9 (MG/DL)	01/09/92	0.63		0.72		0.74	
URIC ACID	2-6 (MG/DL)	01/09/92	4.20		6.00		5.50	
TOT. BILIRUBIN	0.25-1 (MG/DL)	01/09/92	0.62		0.80		0.76	
DIR BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.18		0.18		0.20	
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92	7.00		7.20		7.00	
ALBUMINE	50-64 (%)	01/09/92	58.20		62.30		61.30	
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	206.00		210.00		206.00	
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	142.00		148.00		116.00	
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	3.00		2.70		3.40	
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	10.40 >		8.00		9.50	
GLOBULINS BETA	8-12 (%)	01/09/92	10.60		10.60		11.20	
GLOBULINS GAMMA	14-22 (%)	01/09/92	17.80		16.40		14.60	
TSH	0.35-7 (MU/ML)	01/09/92	2.20					
T4	5-10.6 (UGX)	01/09/92	8.80					

1890

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: S/A Patient: 554 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/09/92		05/11/92		26/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92	14.00		14.00		13.80	
RBC	4500000-6500000 (/UL)	01/09/92	4600000		4770000		4800000	
HBC	4000-10000 (/UL)	01/09/92	6400.00		6200.00		5400.00	
HBC: N	50-70 (%)	01/09/92	61.00		74.00 >		70.00	
HBC: L	20-30 (%)	01/09/92	35.00 >		26.00		28.00	
HBC: E	0-1 (%)	01/09/92	3.00 >>		0.00		0.00	
HBC: M	0-1 (%)	01/09/92	1.00		0.00		2.00 >>	
HBC: B	0-1 (%)	01/09/92	0.00		0.00		0.00	
NA+	135-150 (MEQ/L)	01/09/92	141.00		138.00		140.00	
K+	3.6-5.5 (MEQ/L)	01/09/92	3.90		4.30		4.00	
PO4--	2-6.8 (MEQ/L)	01/09/92	4.10		4.10		4.50	
SGOT	5-29 (U/L)	01/09/92	16.00		14.00		12.00	
SGPT	5-27 (U/L)	01/09/92	9.00		16.00		15.00	
ALK. PHOSPH.	72-244 (MU/ML)	01/09/92	144.00		188.00		203.00	
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	1.48 >>		1.51 >>		1.41 >	
BUN	0.22-0.6 (MG/DL)	01/09/92	0.43		0.40		0.38	
CREATININE	0.9-1.4 (MG/DL)	01/09/92	0.74 <		0.75 <		0.73 <	
URIC ACID	3-7 (MG/DL)	01/09/92	4.00		4.20		4.40	
TOT BILIRUBIN	0.25-1 (MG/DL)	01/09/92	0.78		0.82		0.76	
DIR BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.18		0.12		0.14	
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92	7.80		7.20		7.10	
ALBUMINE	50-64 (%)	01/09/92	66.10 >		53.60		53.20	
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	233.00		244.00		240.00	
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	165.00		170.00		165.00	
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	2.90		2.80		4.00	
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	7.60		8.30		9.70	
GLOBULINS BETA	8-12 (%)	01/09/92	10.40		12.90 >		11.20	
GLOBULINS GAMMA	14-22 (%)	01/09/92	13.00 <		19.70		21.90	
TSH	0.35-7 (MU/ML)	01/09/92	1.70					
T4	5-10.6 (UGx)	01/09/92	7.80					

1891

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: B/A Patient: 555 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/09/92		05/11/92		26/11/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92	13.00		13.00		14.00	
RBC	3500000-5600000 (/UL)	01/09/92						
HBC	4000-10000 (/UL)	01/09/92	4550000		4420000		4900000	
HBC: N	50-70 (%)	01/09/92	6900.00		6400.00		6500.00	
HBC: L	20-30 (%)	01/09/92	70.00		66.00		70.00	
HBC: E	0-1 (%)	01/09/92	30.00		34.00	>	30.00	
HBC: H	0-1 (%)	01/09/92	0.00		0.00		0.00	
HBC: B	0-1 (%)	01/09/92	0.00		0.00		0.00	
NA+	135-150 (MEQ/L)	01/09/92	0.00		0.00		0.00	
K+	3.6-5.5 (MEQ/L)	01/09/92	140.00		140.00		141.00	
PO4--	2-6.8 (MEQ/L)	01/09/92	4.30		4.20		4.40	
SGOT	5-24 (U/L)	01/09/92	3.90		5.03		5.00	
SGPT	5-22 (U/L)	01/09/92	11.00		13.00		12.00	
ALK. PHOSPH.	72-244 (MU/ML)	01/09/92	13.00		15.00		14.00	
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	199.00		177.00		169.00	
BUN	0.22-0.6 (MG/DL)	01/09/92	1.04		0.95		1.44 >>	
CREATININE	0.5-0.9 (MG/DL)	01/09/92	0.34		0.38		0.38	
URIC ACID	2-6 (MG/DL)	01/09/92	0.72		0.68		0.75	
TOT BILIRUBIN	0.25-1 (MG/DL)	01/09/92	3.50		4.00		4.00	
DIR BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.70		0.63		0.76	
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92	0.12		0.13		0.17	
ALBUMINE	50-64 (%)	01/09/92	7.10		7.00		7.00	
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	56.80		60.20		60.20	
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	204.00		195.00		68.00 <	
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	113.00		31.00	<	190.00 >	
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	3.10		3.80		3.90	
GLOBULINS BETA	8-12 (%)	01/09/92	7.40		9.80		9.70	
GLOBULINS GAMMA	14-22 (%)	01/09/92	9.20		11.20		11.00	
TSH	0.35-7 (MU/ML)	01/09/92	23.50	>	15.00		15.20	
T4	5-10.6 (UG%)	01/09/92	9.20	>>				
			1.70	<<				

1892

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 8/A Patient: 556 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/09/92		05/11/92		26/11/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	01/09/92		13.60		13.50		
HT	()	01/09/92						
RBC	4500000-6500000 (/UL)	01/09/92		4600000		4600000		
WBC	4000-10000 (/UL)	01/09/92	6800.00		6600.00			
WBC: N	50-70 (%)	01/09/92	60.00		64.00			
WBC: L	20-30 (%)	01/09/92	40.00	>>	30.50	>		
WBC: E	0-1 (%)	01/09/92	0.00		0.00			
WBC: M	0-1 (%)	01/09/92	0.00		5.60	>>		
WBC: B	0-1 (%)	01/09/92	0.00		0.00			
PLATELETS	()	01/09/92						
NA+	135-150 (MEQ/L)	01/09/92	136.00		144.00		140.00	
K+	3.6-5.5 (MEQ/L)	01/09/92	4.20		4.00		3.90	
CL-	98-115 (MEQ/L)	01/09/92						
Ca++	()	01/09/92						
PO4--	2-6.8 (MEQ/L)	01/09/92	2.90		3.30		3.00	
SGOT	5-29 (U/L)	01/09/92	12.00		11.00		12.00	
SGPT	5-27 (U/L)	01/09/92	19.00		18.00		14.00	
GAMMA GT	()	01/09/92						
LDH	()	01/09/92						
ALK. PHOSPH.	72-244 (NU/ML)	01/09/92	176.00		155.00		166.00	
GLUCOSE	0.76-1.1 (MG/DL)	01/09/92	0.97		0.99		0.91	
BUN	0.22-0.6 (MG/DL)	01/09/92	0.22		0.28		0.28	
UREA	()	01/09/92						
CREATININE	0.9-1.4 (MG/DL)	01/09/92	0.70	<	0.73	<	0.71	
URIC ACID	3-7 (MG/DL)	01/09/92	4.00		4.40		4.00	
TOT BILIRUBIN	0.25-1 (MG/DL)	01/09/92	0.65		0.66		0.68	
DIR BILIRUBIN	0.1-0.25 (MG/DL)	01/09/92	0.14		0.17		0.16	
TOT. PROTEINS	6.5-8 (MG/DL)	01/09/92	6.90		7.10		7.20	
ALBUMINE	50-64 (%)	01/09/92	58.60		61.20		60.30	
TOT. CHOLEST.	130-250 (MG/DL)	01/09/92	176.00		188.00		180.00	
TRIGLYCERIDES	70-172 (MG/DL)	01/09/92	133.00		127.00		112.00	
GLOBULINS ALPHA 1	2-4 (%)	01/09/92	3.80		4.90	>	4.70	
GLOBULINS ALPHA 2	6-10 (%)	01/09/92	9.40		7.70		7.10	
GLOBULINS BETA	8-12 (%)	01/09/92	10.70		10.00		11.30	
GLOBULINS GAMMA	14-22 (%)	01/09/92	17.50		16.40		16.60	
TSH	0.35-7 (MU/ML)	01/09/92	1.40					
T4	5-10.6 (UG%)	01/09/92	5.20				17.70	

1893

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 9 Patient: 241 Treatment: Placebo Sex: Female

			Visit number / Laboratory date
			Screen
			04/02/91
			value (e)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/02/91	13.60
HT	37-47 (%)	01/02/91	39.90
RBC	4.2-5.4 (10 ⁶ /UL)	01/02/91	4.27
WBC	4.8-10.8 (10 ³ /UL)	01/02/91	8.60
WBC: L	20.5-51.1 (%)	01/02/91	23.90
WBC: M	1.7-9.3 (%)	01/02/91	4.90
PLATELETS	130-400 (10 ³ /UL)	01/02/91	425.00 >
NA+	135-148 (MMOL/L)	01/02/91	143.70
K+	3.5-5 (MMOL/L)	01/02/91	4.59
CL-	96-108 (MMOL/L)	01/02/91	106.00
Ca ⁺⁺	2.1-2.6 (MMOL/L)	01/02/91	2.58
SGOT	5-41 (U/L)	01/02/91	13.00
SGPT	6-55 (U/L)	01/02/91	17.00
GAMMA GT	11-50 (U/L)	01/02/91	47.00
LDH	200-460 (U/L)	01/02/91	303.00
ALK. PHOSPH.	90-279 (U/L)	01/02/91	160.00
GLUCOSE	60-105 (MG/DL)	01/02/91	88.00
BUN	10-50 (MG/DL)	01/02/91	29.00
CREATININE	0.5-1.15 (MG/DL)	01/02/91	0.95
TOT. BILIRUBIN	0.1-1 (MG/DL)	01/02/91	0.84
DIR. BILIRUBIN	0.01-0.25 (MG/DL)	01/02/91	0.03
TOT. PROTEINS	6-8 (G/100ML)	01/02/91	7.70
ALBUMINE	3.5-5.5 (G/100ML)	01/02/91	4.67
TOT. CHOLEST.	125-200 (MG/DL)	01/02/91	250.00 >
TRIGLYCERIDES	35-170 (MG/DL)	01/02/91	80.00
GLOBULINS ALPHA 1	0.2-0.4 (G/100ML)	01/02/91	0.22
GLOBULINS ALPHA 2	0.5-0.9 (G/100ML)	01/02/91	0.63
GLOBULINS BETA	0.6-1.1 (G/100ML)	01/02/91	0.91
GLOBULINS GAMMA	0.7-1.7 (G/100ML)	01/02/91	1.27
TSH	0.2-4 (UU/ML)	01/02/91	0.99
T4	50-115 (NG/ML)	01/02/91	110.00

1894

(e) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 242 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory data	
			Screen	Day 21
			12/02/91	11/03/91
			value (◊)	value (◊)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/02/91	13.70	13.30
HT	37-47 (X)	01/02/91	40.20	39.00
RBC	4.2-5.4 (10 ⁶ /UL)	01/02/91	4.30	4.25
WBC	4.8-10.8 (10 ³ /UL)	01/02/91	7.20	9.50
WBC: L	20.5-51.1 (X)	01/02/91	24.90	21.20
WBC: M	1.7-9.3 (X)	01/02/91	2.00	4.10
PLATELETS	130-400 (10 ³ /UL)	01/02/91	348.00	365.00
NA+	135-148 (MMOL/L)	01/02/91	141.00	143.20
K+	3.5-5 (MMOL/L)	01/02/91	4.79	4.73
CL-	96-108 (MMOL/L)	01/02/91	105.00	107.00
Ca++	2.1-2.6 (MMOL/L)	01/02/91		2.27
PO4--	0.8-1.55 (MMOL/L)	01/02/91		1.26
SGOT	5-41 (U/L)	01/02/91	13.00	14.00
SGPT	6-55 (U/L)	01/02/91	22.00	18.00
GAMMA GT	11-50 (U/L)	01/02/91	22.00	13.00
LDH	200-460 (U/L)	01/02/91		279.00
ALK. PHOSPH.	90-279 (U/L)	01/02/91	181.00	139.00
GLUCOSE	60-105 (MG/DL)	01/02/91	107.00 >	88.00
BUN	10-50 (MG/DL)	01/02/91	31.00	30.00
CREATININE	0.5-1.15 (MG/DL)	01/02/91		0.76
URIC ACID	2.5-7 (MG/DL)	01/02/91		3.90
TOT. BILIRUBIN	0.1-1 (MG/DL)	01/02/91	0.82	0.28
DIR. BILIRUBIN	0.01-0.25 (MG/DL)	01/02/91	0.06	0.02
TOT. PROTEINS	6-8 (G/100ML)	01/02/91	6.80	7.00
ALBUMINE	3.5-5.5 (G/100ML)	01/02/91	4.30	4.56
TOT. CHOLEST.	125-200 (MG/DL)	01/02/91	272.00 >>	252.00 >
TRIGLYCERIDES	35-170 (MG/DL)	01/02/91	133.00	97.00
GLOBULINS ALPHA 1	0.2-0.4 (G/100ML)	01/02/91	0.22	0.22
GLOBULINS ALPHA 2	0.5-0.9 (G/100ML)	01/02/91	0.52	0.47 <
GLOBULINS BETA	0.6-1.1 (G/100ML)	01/02/91	0.80	0.74
GLOBULINS GAMMA	0.7-1.7 (G/100ML)	01/02/91	0.95	1.01
TSH	0.2-4 (UU/ML)	01/02/91	1.53	
T4	50-115 (NG/ML)	01/02/91	53.00	

1895

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 9 Patient: 243 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 14	
			15/02/91		06/03/91	
			value	(#)	value	(#)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	23/11/90			13.40	
HT	37-47 (%)	23/11/90			37.70	
RBC	4.2-5.4 (10 ⁶ /UL)	23/11/90			4.33	
WBC	4.8-10.8 (10 ³ /UL)	23/11/90			6.20	
WBC: N	()	23/11/90				
WBC: L	20.5-51.1 (%)	23/11/90			41.00	
WBC: E	()	23/11/90				
WBC: M	1.7-9.3 (%)	23/11/90			4.40	
WBC: B	()	23/11/90				
PLATELETS	130-400 (10 ³ /UL)	23/11/90			189.00	
NA+	135-148 (MMOL/L)	23/11/90	144.80		139.80	
K+	3.5-5 (MMOL/L)	23/11/90	4.67		4.28	
CL-	96-108 (MMOL/L)	23/11/90	105.00		107.00	
Ca++	2.1-2.6 (MMOL/L)	23/11/90			1.17 <<	
PO4--	0.8-1.55 (MMOL/L)	23/11/90			1.19	
SGOT	5-41 (U/L)	23/11/90	21.00		20.00	
SGPT	6-55 (U/L)	23/11/90	20.00		25.00	
GAMMA GT	11-50 (U/L)	23/11/90	12.00		13.00	
LDH	200-460 (U/L)	23/11/90	308.00		327.00	
ALK. PHOSPH.	90-279 (U/L)	23/11/90	188.00		218.00	
GLUCOSE	60-105 (MG/DL)	23/11/90	105.00		108.00 >	
BUN	10-50 (MG/DL)	23/11/90	37.00		37.00	
UREA	()	23/11/90				
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.70		0.71	
URIC ACID	2.5-7 (MG/DL)	23/11/90			4.50	
TOT BILIRUBIN	0.1-1 (NG/DL)	23/11/90	0.47		0.86	
DIR BILIRUBIN	0.01-0.25 (NG/DL)	23/11/90	0.05		0.03	
TOT. PROTEINS	6-8 (G/DL)	23/11/90	6.90		6.90	
ALBUMINE	55-69 (%)	23/11/90	64.60		67.20	
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	209.00 >		178.00	
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	111.00		72.00	
GLOBULINS ALPHA 1	2-4 (%)	23/11/90	2.80		2.70	
GLOBULINS ALPHA 2	6.5-11 (%)	23/11/90	8.00		7.00	
GLOBULINS BETA	7.5-12.5 (%)	23/11/90	12.10		11.40	
GLOBULINS GAMMA	12-24 (%)	23/11/90	12.50		11.70 <	
TSH	0.2-4 (UU/ML)	23/11/90	3.04			
T4	50-115 (NG/ML)	23/11/90	105.00			

1896

(#) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 244 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			14/02/91		12/03/91	
			value	(†)	value	(‡)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/02/91	14.70		14.30	
HT	37-47 (X)	01/02/91	43.00		42.60	
RBC	4.2-5.4 (10 ⁶ /UL)	01/02/91	5.16		5.16	
WBC	4.8-10.8 (10 ³ /UL)	01/02/91	9.50		6.70	
WBC: L	20.5-51.1 (X)	01/02/91	32.80		34.90	
WBC: M	1.7-9.3 (X)	01/02/91	4.00		3.90	
PLATELETS	130-400 (10 ³ /UL)	01/02/91	370.00		323.00	
NA+	135-148 (MMOL/L)	01/02/91	137.50		141.60	
K+	3.5-5 (MMOL/L)	01/02/91	4.28		4.57	
CL-	96-108 (MMOL/L)	01/02/91	102.00		110.00 >	
Ca++	2.1-2.6 (MMOL/L)	01/02/91	2.34		2.29	
PO4--	0.8-1.55 (MMOL/L)	01/02/91			1.02	
SGOT	5-41 (U/L)	01/02/91	17.00		13.00	
SGPT	6-55 (U/L)	01/02/91	24.00		17.00	
GAMMA GT	11-50 (U/L)	01/02/91	29.00		21.00	
LDH	200-460 (U/L)	01/02/91	299.00		263.00	
ALK. PHOSPH.	90-279 (U/L)	01/02/91	253.00		210.00	
GLUCOSE	60-105 (MG/DL)	01/02/91	90.00		103.00	
BUN	10-50 (MG/DL)	01/02/91	34.00		38.00	
CREATININE	0.5-1.15 (MG/DL)	01/02/91	0.86		0.74	
URIC ACID	178-387 (UMOL/L)	01/02/91			184.00	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/02/91	0.59		0.24	
DIR BILIRUBIN	0.01-0.25 (MG/DL)	01/02/91	0.07		0.02	
TOT. PROTEINS	6-8 (G/100ML)	01/02/91	7.20		6.60	
ALBUMINE	3.5-5.5 (G/100ML)	01/02/91	4.61		4.26	
TOT. CHOLEST.	125-200 (MG/DL)	01/02/91	241.00 >		225.00 >	
TRIGLYCERIDES	35-170 (MG/DL)	01/02/91	155.00		184.00 >	
GLOBULINS ALPHA 1	0.2-0.4 (G/100ML)	01/02/91	0.20		0.18 <	
GLOBULINS ALPHA 2	0.5-0.9 (G/100ML)	01/02/91	0.60		0.53	
GLOBULINS BETA	0.6-1.1 (G/100ML)	01/02/91	0.86		0.77	
GLOBULINS GAMMA	0.7-1.7 (G/100ML)	01/02/91	0.93		0.87	
TSH	0.2-4 (UU/ML)	01/02/91	4.31 >			
T4	50-115 (NG/ML)	01/02/91	63.00			

1897

(†) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done (‡) missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 245 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/02/91		15/03/91		05/04/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	23/11/90	12.00		12.00		12.30	
HT	37-47 (%)	23/11/90	35.30 <		35.00 <		36.00 <	
RBC	4.2-5.4 (10 ⁶ /UL)	23/11/90	4.04 <		3.99 <		4.13 <	
HBC	4.8-10.8 (10 ³ /UL)	23/11/90	5.70		5.20		5.60	
HBC: L	20.5-51.1 (%)	23/11/90	28.70		28.00		20.00 <	
HBC: M	1.7-9.3 (%)	23/11/90	7.60		4.20		1.50 <	
PLATELETS	130-400 (10 ³ /UL)	23/11/90	323.00		298.00		302.00	
NA+	135-148 (MMOL/L)	23/11/90	139.60		140.00		140.20	
K+	3.5-5 (MMOL/L)	23/11/90	3.88		3.91		3.77	
CL-	96-108 (MMOL/L)	23/11/90	105.00		109.00 >		107.00	
Ca++	2.1-2.6 (MMOL/L)	23/11/90			2.30		2.45	
PO4--	0.8-1.55 (MMOL/L)	23/11/90			0.96		1.09	
SGOT	5-41 (U/L)	23/11/90	12.00		20.00		20.00	
SGPT	6-55 (U/L)	23/11/90	14.00		24.00		27.00	
GAMMA GT	11-50 (U/L)	23/11/90	13.00		15.00		15.00	
LDH	200-460 (U/L)	23/11/90			220.00		258.00	
ALK. PHOSPH.	90-279 (U/L)	23/11/90	126.00		135.00		146.00	
GLUCOSE	60-105 (MG/DL)	23/11/90	93.00		81.00		106.00 >	
BUN	10-50 (MG/DL)	23/11/90	24.00		32.00		29.00	
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.51		0.53		0.59	
URIC ACID	2.5-7 (MG/DL)	23/11/90			3.00		2.70	
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.37		0.22		0.21	
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.05		0.02		0.04	
TOT. PROTEINS	6-8 (G/DL)	23/11/90	7.40		7.40		8.10 >	
ALBUMINE	55-69 (%)	23/11/90	61.90		61.90		59.90	
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	185.00		218.00 >		231.00 >	
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	71.00		152.00		79.00	
GLOBULINS ALPHA 1	2-4 (%)	23/11/90	3.00		3.60		3.50	
GLOBULINS ALPHA 2	6.5-11 (%)	23/11/90	7.10		6.70		6.80	
GLOBULINS BETA	7.5-12.5 (%)	23/11/90	11.50		12.00		11.70	
GLOBULINS GAMMA	12-24 (%)	23/11/90	16.50		15.80		18.10	
TSH	0.2-4 (UU/ML)	23/11/90	0.99					
T4	50-115 (NG/ML)	23/11/90	114.00					

1898

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 9 Patient: 246 Treatment: Placebo Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date			
			Screen		Day 21	
			13/02/91		15/03/91	
			value	(*)	value	(*)
HB	12-16 (G/DL)	01/02/91	14.60		14.40	
HT	37-47 (%)	01/02/91	43.20		41.20	
RBC	4.2-5.4 (10 ⁶ /UL)	01/02/91	4.85		4.78	
WBC	4.8-10.8 (10 ³ /UL)	01/02/91	8.50		5.00	
WBC: L	20.5-51.1 (%)	01/02/91	18.30	<	26.00	
WBC: M	1.7-9.3 (%)	01/02/91	0.20	<	0.20	<
PLATELETS	130-400 (10 ³ /UL)	01/02/91	207.00		157.00	
NA+	135-148 (MMOL/L)	01/02/91	140.80		137.10	
K+	3.5-5 (MMOL/L)	01/02/91	4.37		3.72	
CL-	96-108 (MMOL/L)	01/02/91	108.00		107.00	
Ca++	2.1-2.6 (MMOL/L)	01/02/91	2.43			
SGOT	5-41 (U/L)	01/02/91	11.00		13.00	
SGPT	6-55 (U/L)	01/02/91	19.00		19.00	
GAMMA GT	11-50 (U/L)	01/02/91	21.00		15.00	
LDH	200-460 (U/L)	01/02/91	358.00		281.00	
ALK. PHOSPH.	90-279 (U/L)	01/02/91	156.00		158.00	
GLUCOSE	60-105 (MG/DL)	01/02/91	85.00		88.00	
BUN	10-50 (MG/DL)	01/02/91	33.00		23.00	
CREATININE	0.5-1.15 (MG/DL)	01/02/91	1.26	>	0.94	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/02/91	0.48		0.42	
DIR BILIRUBIN	0.01-0.25 (MG/DL)	01/02/91	0.04		0.04	
TOT. PROTEINS	6-8 (G/100ML)	01/02/91	7.20		6.40	
ALBUMINE	3.5-5.5 (G/100ML)	01/02/91	4.64		4.29	
TOT. CHOLEST.	125-200 (MG/DL)	01/02/91	204.00	>	195.00	
TRIGLYCERIDES	35-170 (MG/DL)	01/02/91	96.00		53.00	
GLOBULINS ALPHA 1	0.2-0.4 (G/100ML)	01/02/91	0.23		0.17	<
GLOBULINS ALPHA 2	0.5-0.9 (G/100ML)	01/02/91	0.63		0.40	<
GLOBULINS BETA	0.6-1.1 (G/100ML)	01/02/91	0.73		0.56	<
GLOBULINS GAMMA	0.7-1.7 (G/100ML)	01/02/91	0.96		0.97	
TSH	0.2-4 (UU/ML)	01/02/91	1.50			
T4	50-115 (NG/ML)	01/02/91	77.00			

1899

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 18.0
 9550082
 LABORATORY DATA
 Centre: 9 Patient: 247 Treatment: Placebo Sex: Female

			Visit number / Laboratory data			
			Screen		Day 21	
			20/02/91		18/03/91	
			value	(*)	value	(*)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	23/11/90	13.60		12.30	
HT	37-47 (%)	23/11/90	39.20		35.80 <	
RBC	4.2-5.4 (10 ⁶ /UL)	23/11/90	4.42		4.01 <	
WBC	4.8-10.8 (10 ³ /UL)	23/11/90	6.20		4.50 <	
WBC: L	20.5-51.1 (%)	23/11/90	30.10		34.70	
WBC: M	1.7-9.3 (%)	23/11/90	7.00		6.60	
PLATELETS	150-400 (10 ³ /UL)	23/11/90	309.00		283.00	
NA+	135-148 (MMOL/L)	23/11/90	144.00		141.50	
K+	3.5-5 (MMOL/L)	23/11/90	4.00		4.37	
CL-	96-108 (MMOL/L)	23/11/90	85.00	<<	111.00 >	
Ca++	2.1-2.6 (MMOL/L)	23/11/90	2.27		2.37	
PO4--	0.8-1.55 (MMOL/L)	23/11/90			1.18	
SGOT	5-41 (U/L)	23/11/90	23.00		21.00	
SGPT	6-55 (U/L)	23/11/90	22.00		29.00	
GAMMA GT	11-50 (U/L)	23/11/90	24.00		19.00	
LDH	200-460 (U/L)	23/11/90	296.00		206.00	
ALK. PHOSPH.	90-279 (U/L)	23/11/90	191.00		137.00	
GLUCOSE	60-105 (MG/DL)	23/11/90	91.00		72.00	
BUN	10-50 (MG/DL)	23/11/90	14.00		9.00 <	
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.76		0.58	
URIC ACID	2.5-7 (MG/DL)	23/11/90			4.60	
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.68		0.42	
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.13		0.04	
TOT. PROTEINS	6-8 (G/DL)	23/11/90	6.90		6.50	
ALBUMINE	55-69 (%)	23/11/90	59.70		62.80	
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	146.00		183.00	
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	129.00		84.00	
GLOBULINS ALPHA 1	2-4 (%)	23/11/90	3.60		3.30	
GLOBULINS ALPHA 2	6.5-11 (%)	23/11/90	7.50		7.60	
GLOBULINS BETA	7.5-12.5 (%)	23/11/90	9.60		10.40	
GLOBULINS GAMMA	12-24 (%)	23/11/90	19.60		15.90	
TSH	0.2-4 (UU/ML)	23/11/90	1.71			
T4	50-115 (NG/ML)	23/11/90	81.00			

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(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 9 Patient: 248 Treatment: Placebo Sex: Male

			Visit number / Laboratory date	
			Screen	Day 14
			04/03/91	22/03/91
			value (⊕)	value (⊕)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	23/11/90	15.70	14.80
HT	42-52 (X)	23/11/90	45.90	42.70
RBC	4.3-6.1 (10 ⁶ /UL)	23/11/90	5.37	4.99
WBC	4.8-10.8 (10 ³ /UL)	23/11/90	9.80	6.60
WBC: I	20.5-51.1 (X)	23/11/90	10.70	38.60
WBC: M	1.7-9.3 (X)	23/11/90	5.80	7.60
PLATELETS	130-400 (10 ³ /UL)	23/11/90	300.00	284.00
NA+	135-148 (MMOL/L)	23/11/90	139.30	138.80
K+	3.5-5 (MMOL/L)	23/11/90	4.61	4.10
CL-	96-108 (MMOL/L)	23/11/90	104.00	103.00
Ca++	2.1-2.6 (MMOL/L)	23/11/90		2.59
PO4--	0.8-1.55 (MMOL/L)	23/11/90		1.25
SODT	5-41 (U/L)	23/11/90	13.00	21.00
SOPT	6-55 (U/L)	23/11/90	20.00	32.00
GAMMA GT	11-50 (U/L)	23/11/90	20.00	28.00
LDH	200-460 (U/L)	23/11/90		271.00
ALK. PHOSPH.	90-279 (U/L)	23/11/90		212.00
GLUCOSE	60-105 (MG/DL)	23/11/90	74.00	94.00
BUN	10-50 (MG/DL)	23/11/90	24.00	17.00
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.84	0.68
URIC ACID	2.5-7 (MG/DL)	23/11/90	4.90	
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.64	0.60
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.05	0.10
TOT. PROTEINS	6-8 (G/DL)	23/11/90	6.40	7.00
ALBUMINE	55-69 (X)	23/11/90	66.50	68.20
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	246.00	251.00
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	133.00	89.00
GLOBULINS ALPHA 1	2-4 (X)	23/11/90	2.90	3.10
GLOBULINS ALPHA 2	6.5-11 (X)	23/11/90	8.70	8.00
GLOBULINS BETA	7.5-12.5 (X)	23/11/90	10.80	9.70
GLOBULINS GAMMA	12-24 (X)	23/11/90	11.10	11.00

1901

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 249 Treatment: Raboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			04/03/91
			value (d)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	23/11/90	13.70
HT	37-47 (%)	23/11/90	39.10
RBC	4.2-5.4 (10 ⁶ /UL)	23/11/90	4.39
WBC	4.8-10.8 (10 ³ /UL)	23/11/90	8.20
WBC: L	20.5-51.1 (%)	23/11/90	25.80
WBC: M	1.7-9.3 (%)	23/11/90	4.10
PLATELETS	130-400 (10 ³ /UL)	23/11/90	423.00 >
NA+	135-148 (MMOL/L)	23/11/90	136.40
K+	3.5-5 (MMOL/L)	23/11/90	4.23
CL-	96-108 (MMOL/L)	23/11/90	103.00
Ca++	2.1-2.6 (MMOL/L)	23/11/90	2.57
SGOT	5-41 (U/L)	23/11/90	23.00
SGPT	6-55 (U/L)	23/11/90	36.00
GAMMA GT	11-50 (U/L)	23/11/90	51.00 >
LDH	200-460 (U/L)	23/11/90	342.00
ALK. PHOSPH.	90-279 (U/L)	23/11/90	208.00
GLUCOSE	60-105 (MG/DL)	23/11/90	89.00
BUN	10-50 (MG/DL)	23/11/90	89.00 >>
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.65
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.58
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.04
TOT. PROTEINS	6-8 (G/DL)	23/11/90	7.90
ALBUMINE	55-69 (%)	23/11/90	65.60 >>
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	282.00 >>
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	111.00
GLOBULINS ALPHA 1	2-4 (%)	23/11/90	2.70
GLOBULINS ALPHA 2	6.5-11 (%)	23/11/90	8.60
GLOBULINS BETA	7.5-12.5 (%)	23/11/90	11.40
GLOBULINS GAMMA	12-24 (%)	23/11/90	11.70 <
TSH	0.2-4 (UU/ML)	23/11/90	1.43
T4	50-115 (NG/ML)	23/11/90	100.00

1902

(d) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 250 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 28	
			07/03/91		02/04/91		08/04/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/91	12.10		11.10 <	11.80 <		
HT	37-47 (%)	01/03/91	36.20 <		33.40 <	36.40 <		
RBC	4.2-5.4 (10 ⁶ /UL)	01/03/91	4.78		4.36	4.73		
WBC	4.8-10.8 (10 ³ /UL)	01/03/91	4.70	<	6.50	3.70 <		
WBC: L	20.5-51.1 (%)	01/03/91	27.70		26.30	38.20		
WBC: N	1.7-9.3 (%)	01/03/91	6.10		4.60	7.60		
PLATELETS	130-400 (10 ³ /UL)	01/03/91	250.00		243.00	254.00		
NA+	135-148 (MMOL/L)	01/03/91	141.00		140.90	139.30		
K+	3.5-5 (MMOL/L)	01/03/91	4.63		4.11	4.63		
CL-	96-108 (MMOL/L)	01/03/91			109.00 >	105.00		
Ca++	2.1-2.6 (MMOL/L)	01/03/91	2.26		2.23	2.29		
PO4--	0.8-1.55 (MMOL/L)	01/03/91	0.87		1.02	1.18		
SGOT	5-41 (U/L)	01/03/91	11.00		11.00	12.00		
SGPT	6-55 (U/L)	01/03/91	14.00		12.00	13.00		
GAMMA GT	11-50 (U/L)	01/03/91	8.00 <		9.00 <	11.00		
LDH	200-460 (U/L)	01/03/91	273.00		325.00	298.00		
ALK. PHOSPH.	90-279 (U/L)	01/03/91	99.00		103.00	119.00		
GLUCOSE	60-105 (MG/DL)	01/03/91	68.00		79.00	72.00		
BUN	10-50 (MG/DL)	01/03/91	23.00		23.00	24.00		
CREATININE	0.5-1.15 (MG/DL)	01/03/91	0.72		0.74	0.81		
TOT BILIRUBIN	0.1-1 (MG/DL)	01/03/91	0.35		0.30	0.64		
DIR BILIRUBIN	0.01-0.25 (MG/DL)	01/03/91	0.03		0.03	0.09		
TOT. PROTEINS	6-8 (G/100ML)	01/03/91	7.00		7.20	7.60		
ALBUMINE	3.5-5.5 (G/100ML)	01/03/91	4.25		4.38	4.63		
TOT. CHOLEST.	125-200 (MG/DL)	01/03/91	174.00		197.00	224.00 >		
TRIGLYCERIDES	35-170 (MG/DL)	01/03/91	49.00		75.00	85.00		
GLOBULINS ALPHA 1	0.2-0.4 (G/100ML)	01/03/91	0.19 <		0.17 <	0.21		
GLOBULINS ALPHA 2	0.5-0.9 (G/100ML)	01/03/91	0.43 <		0.41 <	0.43 <		
GLOBULINS BETA	0.6-1.1 (G/100ML)	01/03/91	0.77		0.74	0.80		
GLOBULINS GAMMA	0.7-1.7 (G/100ML)	01/03/91	1.37		1.50	1.54		
TSH	0.2-4 (UU/ML)	01/03/91	1.26					
T4	50-115 (NG/ML)	01/03/91	79.00					

1903

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 9 Patient: 251 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			18/03/91		10/04/91	
			value	(*)	value	(*)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	23/11/90	13.50		12.80	
HT	37-47 (X)	23/11/90	40.60		37.90	
RBC	4.2-5.4 (10 ⁶ /UL)	23/11/90	4.64		4.35	
WBC	4.8-10.8 (10 ³ /UL)	23/11/90	7.10		7.50	
WBC: L	20.5-51.1 (X)	23/11/90	30.00		31.30	
WBC: M	1.7-9.3 (X)	23/11/90	10.00	>	3.80	
PLATELETS	130-400 (10 ³ /UL)	23/11/90	391.00		353.00	
NA+	135-148 (MMOL/L)	23/11/90	139.50		140.30	
K+	3.5-5 (MMOL/L)	23/11/90	4.75		4.45	
CL-	96-108 (MMOL/L)	23/11/90	105.00		106.00	
Ca++	2.1-2.6 (MMOL/L)	23/11/90			2.40	
PO4--	0.8-1.55 (MMOL/L)	23/11/90			1.34	
SGOT	5-41 (U/L)	23/11/90	11.00		14.00	
SGPT	6-55 (U/L)	23/11/90	15.00		15.00	
GAMMA GT	11-50 (U/L)	23/11/90	9.00	<	9.00	
LDH	200-460 (U/L)	23/11/90	231.00		221.00	
ALK. PHOSPH.	90-279 (U/L)	23/11/90	107.00		137.00	
GLUCOSE	60-105 (MG/DL)	23/11/90	88.00		78.00	
BUN	10-50 (MG/DL)	23/11/90	23.00		25.00	
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.88		0.87	
URIC ACID	2.5-7 (MG/DL)	23/11/90			3.60	
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.26		0.34	
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.03		0.04	
TOT. PROTEINS	6-8 (G/DL)	23/11/90	6.70		6.70	
ALBUMINE	55-69 (X)	23/11/90	65.60		65.60	
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	202.00	>	189.00	
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	85.00		48.00	
GLOBULINS ALPHA 1	2-4 (X)	23/11/90	2.60		3.60	
GLOBULINS ALPHA 2	6.5-11 (X)	23/11/90	7.80		7.20	
GLOBULINS BETA	7.5-12.5 (X)	23/11/90	10.70		10.10	
GLOBULINS GAMMA	12-24 (X)	23/11/90	13.30		13.50	
TSH	0.2-4 (UU/ML)	23/11/90	1.90			
T4	50-115 (NG/ML)	23/11/90	77.00			

1904

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 252 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			28/03/91		20/04/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	23/11/90	13.40		14.20	
HT	37-47 (%)	23/11/90	39.10		42.60	
RBC	4.2-5.4 (10 ⁶ /UL)	23/11/90	4.51		4.87	
WBC	4.8-10.8 (10 ³ /UL)	23/11/90	9.10		9.10	
WBC: L	20.5-51.1 (%)	23/11/90	48.00		34.00	
WBC: M	1.7-9.3 (%)	23/11/90	4.00		2.00	
PLATELETS	130-400 (10 ³ /UL)	23/11/90	273.00		371.00	
NA+	135-148 (MMOL/L)	23/11/90	143.80		141.70	
K+	3.5-5 (MMOL/L)	23/11/90	3.40	<	3.48	
CL-	96-108 (MMOL/L)	23/11/90	95.00	<	103.00	
Ca++	2.1-2.6 (MMOL/L)	23/11/90	2.25		2.35	
PO4--	0.8-1.55 (MMOL/L)	23/11/90			1.48	
SGOT	5-41 (U/L)	23/11/90	15.00		14.00	
SGPT	6-55 (U/L)	23/11/90	13.00		14.00	
GAMMA GT	11-50 (U/L)	23/11/90	29.00		35.00	
LDH	200-460 (U/L)	23/11/90	307.00		305.00	
ALK. PHOSPH.	90-279 (U/L)	23/11/90	236.00		195.00	
GLUCOSE	60-105 (MG/DL)	23/11/90	94.00		111.00	
BUN	10-50 (MG/DL)	23/11/90	29.00		37.00	
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.80		0.91	
URIC ACID	2.5-7 (MG/DL)	23/11/90			8.70	
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.40		0.34	
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.09		0.05	
TOT. PROTEINS	6-8 (G/DL)	23/11/90	7.30		7.80	
ALBUMINE	55-69 (%)	23/11/90	53.30	<	55.30	
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	208.00	>	210.00	
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	139.00		111.00	
GLOBULINS ALPHA 1	2-4 (%)	23/11/90	2.90		2.60	
GLOBULINS ALPHA 2	6.5-11 (%)	23/11/90	9.80		9.10	
GLOBULINS BETA	7.5-12.5 (%)	23/11/90	14.10	>	14.10	
GLOBULINS GAMMA	12-24 (%)	23/11/90	19.90		18.90	
TSH	0.2-4 (UU/NL)	23/11/90	3.60			
T4	50-115 (NG/NL)	23/11/90	83.00			

1905

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 253 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			29/03/91
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/03/91	13.80
HT	37-47 (%)	01/03/91	39.90
RBC	4.2-5.4 (10 ⁶ /UL)	01/03/91	4.42
WBC	4.8-10.8 (10 ³ /UL)	01/03/91	6.10
WBC: L	20.5-51.1 (%)	01/03/91	30.80
WBC: M	1.7-9.3 (%)	01/03/91	6.20
PLATELETS	130-400 (10 ³ /UL)	01/03/91	267.00
NA+	135-148 (MMOL/L)	01/03/91	142.00
K+	3.5-5 (MMOL/L)	01/03/91	3.84
CL-	96-108 (MMOL/L)	01/03/91	107.00
Ca++	2.1-2.6 (MMOL/L)	01/03/91	2.30
PO4--	0.8-1.55 (MMOL/L)	01/03/91	0.75 <
SGOT	5-41 (U/L)	01/03/91	11.00
SGPT	6-55 (U/L)	01/03/91	14.00
GAMMA GT	11-50 (U/L)	01/03/91	12.00
LDH	200-460 (U/L)	01/03/91	247.00
ALK. PHOSPH.	90-279 (U/L)	01/03/91	107.00
GLUCOSE	60-105 (MG/DL)	01/03/91	90.00
BUN	10-50 (MG/DL)	01/03/91	30.00
CREATININE	0.5-1.15 (MG/DL)	01/03/91	0.75
TOT BILIRUBIN	0.1-1 (MG/DL)	01/03/91	0.88
DIR BILIRUBIN	0.01-0.25 (MG/DL)	01/03/91	0.06
TOT. PROTEINS	6-8 (G/100ML)	01/03/91	6.40
ALBUMINE	3.5-5.5 (G/100ML)	01/03/91	4.39
TOT. CHOLEST.	125-200 (MG/DL)	01/03/91	164.00
TRIGLYCERIDES	35-170 (MG/DL)	01/03/91	104.00
GLOBULINS ALPHA 1	0.2-0.4 (G/100ML)	01/03/91	0.17 <
GLOBULINS ALPHA 2	0.5-0.9 (G/100ML)	01/03/91	0.45 <
GLOBULINS BETA	0.6-1.1 (G/100ML)	01/03/91	0.61
GLOBULINS GAMMA	0.7-1.7 (G/100ML)	01/03/91	0.78
TSH	0.2-4 (UU/ML)	01/03/91	1.85
T4	50-115 (NG/ML)	01/03/91	84.00

1906

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 254 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 14	
			05/04/91		08/05/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	23/11/90	13.70		14.00	
HT	37-47 (%)	23/11/90	40.20		41.60	
RBC	4.2-5.4 (10 ⁶ /UL)	23/11/90	4.37		4.56	
MBC	4.8-10.8 (10 ³ /UL)	23/11/90	9.70		12.70 >	
MBC: L	20.5-51.1 (%)	23/11/90	31.90		25.70	
MBC: M	1.7-9.3 (%)	23/11/90	1.80		2.70	
PLATELETS	130-400 (10 ³ /UL)	23/11/90	236.00		250.00	
NA+	135-148 (MMOL/L)	23/11/90	139.50		140.40	
K+	3.5-5 (MMOL/L)	23/11/90	4.46		4.78	
CL-	96-108 (MMOL/L)	23/11/90	105.00		103.00	
Ca++	2.1-2.6 (MMOL/L)	23/11/90	2.41		2.46	
PO4--	0.8-1.55 (MMOL/L)	23/11/90			1.57 >	
SGOT	5-41 (U/L)	23/11/90	15.00		15.00	
SGPT	6-55 (U/L)	23/11/90	12.00		11.00	
GAMMA GT	11-50 (U/L)	23/11/90	37.00		39.00	
LDH	200-460 (U/L)	23/11/90	256.00		335.00	
ALK. PHOSPH.	90-279 (U/L)	23/11/90	93.00		99.00	
GLUCOSE	60-105 (MG/DL)	23/11/90	96.00		83.00	
BUN	10-50 (MG/DL)	23/11/90	29.00		26.00	
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.81		0.87	
URIC ACID	2.5-7 (MG/DL)	23/11/90			5.40	
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.40		0.45	
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.14		0.04	
TOT. PROTEINS	6-8 (G/DL)	23/11/90	6.90		7.40	
ALBUMINE	55-69 (%)	23/11/90	62.80		61.10	
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	274.00 >>		272.00 >>	
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	367.00 >>		282.00 >>	
GLOBULINS ALPHA 1	2-4 (%)	23/11/90	3.60		3.10	
GLOBULINS ALPHA 2	6.5-11 (%)	23/11/90	9.60		10.50	
GLOBULINS BETA	7.5-12.5 (%)	23/11/90	12.40		12.80 >	
GLOBULINS GAMMA	12-24 (%)	23/11/90	11.90 <		12.50	
TSH	0.2-4 (UU/ML)	23/11/90	2.84			
T4	50-115 (NG/ML)	23/11/90	70.00			

1907

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 255 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			08/05/91		03/06/91	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/05/91	11.40	<	11.80 <	
HT	37-47 (X)	01/05/91	35.40	<	35.70 <	
RBC	4.2-5.4 (10 ⁶ /UL)	01/05/91	4.79		4.92	
HBC	4.8-10.8 (10 ³ /UL)	01/05/91	8.30		8.80	
HBC: L	20.5-51.1 (X)	01/05/91	32.40		30.80	
HBC: H	1.7-9.3 (X)	01/05/91	4.00		4.70	
PLATELETS	130-400 (10 ³ /UL)	01/05/91	396.00		406.00 >	
NA+	135-148 (MMOL/L)	01/05/91	138.90		136.80	
K+	3.5-5 (MMOL/L)	01/05/91	3.85		3.94	
CL-	96-108 (MMOL/L)	01/05/91	109.00	>	102.00	
Ca++	2.1-2.6 (MMOL/L)	01/05/91	2.30		2.30	
PO4--	0.8-1.55 (MMOL/L)	01/05/91			1.28	
SGOT	5-41 (U/L)	01/05/91	14.00		13.00	
SGPT	6-55 (U/L)	01/05/91	14.00		14.00	
GAMMA GT	11-50 (U/L)	01/05/91	22.00		14.00	
LDH	200-460 (U/L)	01/05/91	266.00		242.00	
ALK. PHOSPH.	90-279 (U/L)	01/05/91	249.00		241.00	
GLUCOSE	60-105 (MG/DL)	01/05/91	76.00		80.00	
BUN	10-50 (MG/DL)	01/05/91	27.00		31.00	
CREATININE	0.5-1.15 (MG/DL)	01/05/91	0.84		0.78	
URIC ACID	2.5-7 (MG/DL)	01/05/91			2.90	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/05/91	0.40		0.17	
DIR BILIRUBIN	0.01-0.25 (MG/DL)	01/05/91	0.09		0.04	
TOT. PROTEINS	6-8 (G/100ML)	01/05/91	8.00		7.60	
ALBUMINE	3.5-5.5 (G/100ML)	01/05/91	4.86		4.40	
TOT. CHOLEST.	125-200 (MG/DL)	01/05/91	135.00		111.00 <	
TRIGLYCERIDES	35-170 (MG/DL)	01/05/91	54.00		36.00	
GLOBULINS ALPHA 1	0.2-0.4 (G/100ML)	01/05/91	0.18	<	0.25	
GLOBULINS ALPHA 2	0.5-0.9 (G/100ML)	01/05/91	0.53		0.50	
GLOBULINS BETA	0.6-1.1 (G/100ML)	01/05/91	0.87		0.79	
GLOBULINS GAMMA	0.7-1.7 (G/100ML)	01/05/91	1.56		1.65	
TSH	0.2-4 (UU/ML)	01/05/91	1.43			
T4	50-115 (NG/ML)	01/05/91	106.00			

1908

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 256 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 42
			23/05/91	02/07/91
Laboratory test	Range value	Range date	value (φ)	value (φ)
HB	12-16 (G/DL)	23/11/90	13.90	13.40
HT	37-47 (%)	23/11/90	41.00	38.50
RBC	4.2-5.4 (10 ⁶ /UL)	23/11/90	4.43	4.08 <
MBC	4.8-10.8 (10 ³ /UL)	23/11/90	6.50	5.30
MBC: L	20.5-51.1 (%)	23/11/90	24.30	24.80
MBC: M	1.7-9.3 (%)	23/11/90	6.00	7.50
PLATELETS	130-400 (10 ³ /UL)	23/11/90	331.00	316.00
NA+	135-148 (MMOL/L)	23/11/90	139.60	137.50
K+	3.5-5 (MMOL/L)	23/11/90	3.87	3.93
CL-	96-108 (MMOL/L)	23/11/90	101.00	101.00
Ca++	2.1-2.6 (MMOL/L)	23/11/90		2.30
SGOT	5-41 (U/L)	23/11/90	17.00	14.00
SGPT	6-55 (U/L)	23/11/90	15.00	15.00
GAMMA GT	11-50 (U/L)	23/11/90	20.00	25.00
LDH	200-460 (U/L)	23/11/90		303.00
ALK. PHOSPH.	90-279 (U/L)	23/11/90	135.00	166.00
GLUCOSE	60-105 (MG/DL)	23/11/90	91.00	99.00
BUN	10-50 (MG/DL)	23/11/90	27.00	35.00
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.84	0.84
URIC ACID	2.5-7 (MG/DL)	23/11/90		2.90
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.65	0.49
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.05	0.04
TOT. PROTEINS	6-8 (G/DL)	23/11/90	7.30	7.10
ALBUMINE	55-69 (%)	23/11/90	64.90	69.40 >
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	216.00 >	251.00 >
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90		100.00
GLOBULINS ALPHA 1	2-4 (%)	23/11/90	2.70	1.70 <
GLOBULINS ALPHA 2	6.5-11 (%)	23/11/90	5.90 <	4.00 <<
GLOBULINS BETA	7.5-12.5 (%)	23/11/90	9.20	7.90
GLOBULINS GAMMA	12-24 (%)	23/11/90	17.30	17.00
TSH	0.2-4 (UU/ML)	23/11/90	2.21	
T4	50-115 (NG/ML)	23/11/90	94.00	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 9 Patient: 257 Treatment: Placebo Sex: Male

			Visit number / Laboratory date
			Screen
			21/06/91
			value (c)
Laboratory test	Range value	Range date	
HB	14-18 (G/DL)	23/11/90	16.40
HT	42-52 (%)	23/11/90	47.60
RBC	4.3-6.1 (10 ⁶ /UL)	23/11/90	5.09
WBC	4.8-10.8 (10 ³ /UL)	23/11/90	8.40
WBC: L	20.5-51.1 (%)	23/11/90	37.10
WBC: M	1.7-9.3 (%)	23/11/90	4.80
PLATELETS	130-400 (10 ³ /UL)	23/11/90	208.00
NA+	135-148 (MMOL/L)	23/11/90	138.40
K+	3.5-5 (MMOL/L)	23/11/90	3.92
CL-	96-108 (MMOL/L)	23/11/90	108.00
SGOT	5-41 (U/L)	23/11/90	17.00
SGPT	6-55 (U/L)	23/11/90	21.00
GAMMA GT	11-50 (U/L)	23/11/90	13.00
LDH	200-460 (U/L)	23/11/90	275.00
ALK. PHOSPH.	90-279 (U/L)	23/11/90	142.00
GLUCOSE	60-105 (MG/DL)	23/11/90	75.00
BUN	10-50 (MG/DL)	23/11/90	33.00
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.91
URIC ACID	2.5-7 (MG/DL)	23/11/90	6.40
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.63
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.14
TOT. PROTEINS	6-8 (G/DL)	23/11/90	7.00
ALBUMINE	55-69 (%)	23/11/90	64.90
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	157.00
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	127.00
GLOBULINS ALPHA 1	2-4 (%)	23/11/90	1.50 <
GLOBULINS ALPHA 2	6.5-11 (%)	23/11/90	5.40 <
GLOBULINS BETA	7.5-12.5 (%)	23/11/90	8.80
GLOBULINS GAMMA	12-24 (%)	23/11/90	19.40

1910

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 9 Patient: 258 Treatment: Placebo Sex: Male

			Visit number / Laboratory date
			Screen
			26/06/91
			value (⊕)
Laboratory test	Range value	Range date	
HB	14-18 (G/DL)	23/11/90	14.70
HT	42-52 (X)	23/11/90	43.60
RBC	4.3-6.1 (10 ⁶ /UL)	23/11/90	4.90
WBC	4.8-10.8 (10 ³ /UL)	23/11/90	5.80
WBC: L	20.5-51.1 (%)	23/11/90	39.10
WBC: M	1.7-9.3 (%)	23/11/90	3.70
PLATELETS	130-400 (10 ³ /UL)	23/11/90	215.00
NA+	135-148 (MMOL/L)	23/11/90	139.10
K+	3.5-5 (MMOL/L)	23/11/90	3.71
CL-	96-108 (MMOL/L)	23/11/90	102.00
Ca++	2.1-2.6 (MMOL/L)	23/11/90	2.34
PO4--	0.8-1.55 (MMOL/L)	23/11/90	1.29
SGOT	5-41 (U/L)	23/11/90	16.00
SGPT	6-55 (U/L)	23/11/90	13.00
GAMMA GT	11-50 (U/L)	23/11/90	16.00
GLUCOSE	60-105 (MG/DL)	23/11/90	90.00
BUN	10-50 (MG/DL)	23/11/90	29.00
CREATININE	0.5-1.15 (MG/DL)	23/11/90	0.98
URIC ACID	2.5-7 (MG/DL)	23/11/90	4.80
TOT BILIRUBIN	0.1-1 (MG/DL)	23/11/90	0.65
DIR BILIRUBIN	0.01-0.25 (MG/DL)	23/11/90	0.10
TOT. PROTEINS	6-8 (G/100ML)	23/11/90	7.10
ALBUMINE	3.5-5.5 (G/100ML)	23/11/90	4.62
TOT. CHOLEST.	125-200 (MG/DL)	23/11/90	206.00 >
TRIGLYCERIDES	35-170 (MG/DL)	23/11/90	198.00 >
GLOBULINS ALPHA 1	2-4 (X)	23/11/90	1.30 <<
GLOBULINS ALPHA 2	6.5-11 (X)	23/11/90	4.80 <
GLOBULINS BETA	7.5-12.5 (X)	23/11/90	9.70
GLOBULINS GAMMA	12-24 (X)	23/11/90	19.10
TSH	0.2-4 (UU/ML)	23/11/90	1.50
T4	50-115 (NG/ML)	23/11/90	75.00

1911

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 319 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/07/91		22/08/91		12/09/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	15.10		15.40		14.70	
HT	40-45 (%)	23/07/91	43.10		43.60			
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.69		4.80		4.52	
HBC	4-11 (10 ⁹ /L)	23/07/91	10.20		9.50		8.10	
HBC: N	40-75 (%)	23/07/91			69.80		65.00	
HBC: L	20-45 (%)	23/07/91	23.10		27.40		28.00	
HBC: E	1-6 (%)	23/07/91			2.00		1.00	
HBC: M	2-10 (%)	23/07/91	2.90		2.80		5.00	
HBC: S	0-1 (%)	23/07/91			0.00		1.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	255.00		259.00		265.00	
NA+	135-145 (MMOL/L)	23/07/91	141.00		139.00		139.00	
K+	3.5-5 (MMOL/L)	23/07/91	3.90		4.20		4.30	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.50		2.42		2.31	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.04		1.38		1.59 >	
SGOT	3-40 (U/L)	23/07/91	20.00		20.00		15.00 >	
SGPT	9-40 (U/L)	23/07/91	16.00		128.00 >>		17.00 >	
GAMMA GT	10-60 (U/L)	23/07/91	16.00		18.00		15.00 >	
LDH	80-210 (U/L)	23/07/91	148.00		128.00		136.00 >	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	136.00		136.00		117.00 >	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	4.70		5.40		4.50 >	
BUN	2.5-6.5 (MMOL/L)	23/07/91	4.90		5.40		5.00 >	
CREATININE	50-110 (UMOL/L)	23/07/91	98.00		100.00		94.00 >	
URIC ACID	155-405 (UMOL/L)	23/07/91	249.00		203.00		349.00 >	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	10.00		13.00		5.00 >	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	3.00		5.00		2.00 >	
TOT. PROTEINS	56-85 (G/L)	23/07/91	75.00		76.00		74.00 >	
ALBUMINE	38-50 (G/L)	23/07/91	49.00		49.00		46.00 >	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	7.20 >		7.50 >		7.60 >	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91			1.40		1.90 >	
TSH	0.4-4 (MU/L)	23/07/91	0.60					
T4	8.5-19 (PMOL/L)	23/07/91	16.10					

1912

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 11 Patient: 320 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/08/91		05/09/91		26/09/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	15.80		16.00		16.10	
HT	40-45 (%)	23/07/91	45.80	>			46.90 >	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	6.03		6.39			
WBC	4-11 (10 ⁹ /L)	23/07/91	6.40		6.30		7.30	
WBC: N	40-75 (%)	23/07/91	62.00		56.00		55.00	
WBC: L	20-45 (%)	23/07/91	31.00		41.00		40.00	
WBC: E	1-6 (%)	23/07/91	2.00		1.00		2.00	
WBC: M	2-10 (%)	23/07/91	5.00		2.00		3.00	
WBC: B	0-1 (%)	23/07/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	325.00		263.00		300.00	
NA+	135-145 (MMOL/L)	23/07/91	144.00		140.00		140.00	
K+	3.5-5 (MMOL/L)	23/07/91	4.70		4.20		5.00	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.48		2.35		2.62 >	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.09		0.88		0.90	
SGOT	3-40 (U/L)	23/07/91	21.00		33.00		36.00	
SGPT	9-40 (U/L)	23/07/91	24.00		19.00		22.00	
GAMMA GT	10-60 (U/L)	23/07/91	14.00		16.00		18.00	
LDH	80-210 (U/L)	23/07/91	117.00				147.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	173.00		188.00		158.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	5.20		4.40		5.10	
BUN	2.5-6.5 (MMOL/L)	23/07/91	4.80		5.20		5.90	
CREATININE	50-110 (UMOL/L)	23/07/91	96.00		103.00		96.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	193.00		262.00		359.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	26.00	>	19.00	>	20.00 >	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	9.00	>	6.00	>	6.00 >	
TOT. PROTEINS	56-85 (G/L)	23/07/91	82.00				80.00	
ALBUMINE	38-50 (G/L)	23/07/91	50.00		46.00		48.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	5.80		6.40		7.70 >	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	0.90		1.90		1.30	
TSH	0.4-4 (MU/L)	23/07/91	0.40					
T4	8.5-19 (PMOL/L)	23/07/91	15.60					

1913

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 321 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/08/91		26/09/91		17/10/91	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	15.80		15.30		15.80	
HT	40-45 (X)	23/07/91			42.80		46.10 >	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.92		4.65		5.05	
WBC	4-11 (10 ⁹ /L)	23/07/91	9.00		8.70		10.40	
WBC: N	40-75 (X)	23/07/91			57.00		71.00	
WBC: L	20-45 (X)	23/07/91	34.90		38.00		28.00	
WBC: E	1-6 (X)	23/07/91			1.00		1.00	
WBC: M	2-10 (X)	23/07/91	6.20		4.00		0.00 <	
WBC: B	0-1 (X)	23/07/91			0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	294.00		280.00		325.00	
NA+	135-145 (MMOL/L)	23/07/91	143.00		143.00			
K+	3.5-5 (MMOL/L)	23/07/91	4.60		4.40			
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.42		2.38			
PO4--	0.8-1.4 (MMOL/L)	23/07/91	0.96		0.74		<	
SGOT	3-40 (U/L)	23/07/91	17.00		17.00			
SGPT	9-40 (U/L)	23/07/91	15.00		67.00		>	
GAMMA GT	10-60 (U/L)	23/07/91	21.00		19.00			
LDH	80-240 (U/L)	23/07/91	136.00		151.00			
ALK. PHOSPH.	100-275 (U/L)	23/07/91	237.00		199.00			
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	5.40		6.10			
BUN	2.5-6.5 (MMOL/L)	23/07/91	6.30		8.00		>	
CREATININE	50-110 (UMOL/L)	23/07/91	87.00		90.00			
URIC ACID	155-405 (UMOL/L)	23/07/91	199.00		202.00			
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	7.00		8.00			
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	4.00		2.00			
TOT. PROTEINS	56-85 (G/L)	23/07/91	78.00		69.00			
ALBUMINE	38-50 (G/L)	23/07/91	49.00		44.00			
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	8.60	>	8.70	>		
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	2.40	>	1.80			
TSH	0.4-4 (MU/L)	23/07/91	1.40					
T4	8.5-19 (PMOL/L)	23/07/91	11.20					

1914

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 322 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			19/09/91		17/10/91		07/11/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HE	13-18 (G/DL)	23/07/91	14.70		14.50		13.80	
HT	37-47 (%)	23/07/91		43.70				
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.47	<	4.67		4.41 <	
WBC	4-11 (10 ⁹ /L)	23/07/91	5.90		6.10		6.50	
WBC: N	40-75 (%)	23/07/91	56.00		63.00		78.00 >	
WBC: L	20-45 (%)	23/07/91	35.00		35.00		20.00	
WBC: E	1-6 (%)	23/07/91	6.00		1.00		0.00 <	
WBC: M	2-10 (%)	23/07/91	3.00		1.00	<	1.00 <	
WBC: B	0-1 (%)	23/07/91	0.00		0.00		1.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	334.00				325.00	
NA+	135-145 (MMOL/L)	23/07/91	139.00		140.00		145.00	
K+	3.5-5 (MMOL/L)	23/07/91	5.00		4.70		5.10 >	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.46		2.35		2.47	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.04		1.19		1.21	
SGOT	3-40 (U/L)	23/07/91	20.00		14.00		18.00	
SGPT	9-40 (U/L)	23/07/91	9.00		10.00		17.00	
GAMMA GT	10-60 (U/L)	23/07/91	33.00		20.00		23.00	
LDH	80-240 (U/L)	23/07/91	165.00		134.00		145.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	149.00		149.00		177.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	5.50		4.80			
BUN	2.5-6.5 (MMOL/L)	23/07/91	7.20	>	7.40	>	6.40	
CREATININE	50-110 (UMOL/L)	23/07/91	90.00		102.00		87.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	150.00	<	203.00		213.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	10.00		6.00		7.00	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	4.00		4.00		2.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	76.00		65.00		66.00	
ALBUMINE	38-50 (G/L)	23/07/91	49.00		46.00		49.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	6.50		6.50		6.20	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	2.20	>	1.20		1.20	
TSH	0.4-4 (MU/L)	23/07/91	3.20					
T4	8.5-19 (PMOL/L)	23/07/91	9.10					

1915

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 323 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/11/91		05/12/91		27/12/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	14.90		17.30		16.60	
HT	40-45 (%)	23/07/91			50.70	>		
RBC	4.5-6.5 (10-12/L)	23/07/91	4.50		5.26		5.06	
WBC	4-11 (10-9/L)	23/07/91	5.60		6.70		6.80	
WBC: N	40-75 (%)	23/07/91	87.00	>	70.00		66.00	
WBC: L	20-45 (%)	23/07/91	13.00	<<	26.00		32.00	
WBC: E	1-6 (%)	23/07/91	0.00	<	1.00		1.00	
WBC: M	2-10 (%)	23/07/91	0.00	<	3.00		1.00	
WBC: B	0-1 (%)	23/07/91	0.00		0.00		0.00	
PLATELETS	150-400 (10-9/L)	23/07/91	207.00		266.00		296.00	
NA+	135-145 (MMOL/L)	23/07/91	142.00		142.00		142.00	
K+	3.5-5 (MMOL/L)	23/07/91	4.70		5.20	>	4.40	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.37		2.34		2.43	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.07		1.16		1.03	
SGOT	3-40 (U/L)	23/07/91	18.00		21.00		28.00	
SGPT	9-40 (U/L)	23/07/91	15.00		25.00			
GAMMA GT	10-60 (U/L)	23/07/91	51.00		58.00		44.00	
LDH	80-210 (U/L)	23/07/91	131.00		166.00			
ALK. PHOSPH.	100-275 (U/L)	23/07/91	114.00		155.00		149.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	6.00		3.90		4.70	
BUN	2.5-6.5 (MMOL/L)	23/07/91	3.50		3.60		3.30	
CREATININE	50-110 (UMOL/L)	23/07/91	87.00		86.00		85.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	336.00		368.00		342.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	12.00		17.00			
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	3.00		2.00		3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	72.00		87.00	>	79.00	
ALBUMINE	38-50 (G/L)	23/07/91	50.00		59.00	>	55.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	5.60		6.90	>	6.60	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	2.80	>>	6.80	>>	3.30	
TSH	0.4-4 (MU/L)	23/07/91	1.50					

1916

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 324 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/11/91		27/12/91		16/01/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	15.30		15.60		14.60	
HT	40-45 (X)	23/07/91	45.40 >				41.90	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	5.12		5.22		4.82	
WBC	4-11 (10 ⁹ /L)	23/07/91	4.50		4.30		3.30 <	
WBC: N	40-75 (X)	23/07/91	62.00		73.00		45.00	
WBC: L	20-45 (X)	23/07/91	32.00		20.00		48.00 >	
WBC: E	1-6 (X)	23/07/91	1.00		0.00 <		0.00 <	
WBC: M	2-10 (X)	23/07/91	4.00		1.00 <		7.00	
WBC: B	0-1 (X)	23/07/91	1.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	352.00		313.00		332.00	
NA+	135-145 (MMOL/L)	23/07/91	141.00		143.00		140.00	
K+	3.5-5 (MMOL/L)	23/07/91	5.10 >		4.40		4.60	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.39		2.13		2.22	
PO4--	0.8-1.4 (MMOL/L)	23/07/91					1.02	
SGOT	3-40 (U/L)	23/07/91	28.00				24.00	
SGPT	9-40 (U/L)	23/07/91	21.00		22.00		33.00	
GAMMA GT	10-60 (U/L)	23/07/91	23.00		25.00		26.00	
LDH	80-210 (U/L)	23/07/91	139.00				148.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	125.00		108.00		108.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	5.10		4.80		4.60	
BUN	2.5-6.5 (MMOL/L)	23/07/91	5.30		5.30		4.20	
CREATININE	50-110 (UMOL/L)	23/07/91	109.00		111.00 >		110.00	
URIC ACID	155-405 (UMOL/L)	23/07/91					342.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	13.00		11.00		11.00	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91					3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	73.00		51.00 <		70.00	
ALBUMINE	38-50 (G/L)	23/07/91	53.00 >		51.00 >		52.00 >	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91			6.00		6.10	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	1.30				0.90	
TSH	0.4-4 (MU/L)	23/07/91	1.60					
T4	8.5-19 (PMOL/L)	23/07/91	16.00					

1917

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 11 Patient: 325 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/12/91		02/01/92		23/01/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	14.00		14.40		14.40	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.99		5.04		4.94	
WBC	4-11 (10 ⁹ /L)	23/07/91	3.90	<	5.40		4.30	
WBC: N	40-75 (%)	23/07/91	73.00		88.00	>	79.00	
WBC: L	20-45 (%)	23/07/91	23.60		12.00	<<	19.00	
WBC: E	1-6 (%)	23/07/91	0.00	<	0.00	<	0.00	
WBC: M	2-10 (%)	23/07/91	3.40		0.00	<	1.00	
WBC: B	0-1 (%)	23/07/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	265.00		283.00		254.00	
NA+	135-145 (MMOL/L)	23/07/91	146.00	>	146.00	>	142.00	
K+	3.5-5 (MMOL/L)	23/07/91			4.90		5.20	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.35		2.28		2.36	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.29		1.22			
SGOT	3-40 (U/L)	23/07/91	26.00		38.00		25.00	
SGPT	9-40 (U/L)	23/07/91	22.00		22.00		37.00	
GAMMA GT	10-60 (U/L)	23/07/91	25.00		33.00		35.00	
LDH	80-210 (U/L)	23/07/91	158.00		174.00		152.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	150.00		196.00		198.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	4.70		4.90		4.30	
BUN	2.5-6.5 (MMOL/L)	23/07/91	8.00	>	7.90	>	8.60	
CREATININE	50-140 (UMOL/L)	23/07/91	111.00	>	104.00		109.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	262.00		330.00		346.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	8.00		10.00		7.00	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91			3.00		2.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	69.00		66.00		70.00	
ALBUMINE	38-50 (G/L)	23/07/91	49.00		48.00		49.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	7.60	>	6.50		7.40	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	1.50		1.40		3.00	
TSH	0.4-4 (MU/L)	23/07/91	0.60				>>	

1918

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 11 Patient: 326 Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			14/01/92		06/02/92	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	13-18 (G/DL)	23/07/91	15.70		16.10	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	5.02		5.05	
WBC	4-11 (10 ⁹ /L)	23/07/91	8.80		9.80	
WBC: N	40-75 (%)	23/07/91	57.00		75.00	
WBC: L	20-45 (%)	23/07/91	38.00		20.00	
WBC: E	1-6 (%)	23/07/91	2.00		2.00	
WBC: M	2-10 (%)	23/07/91	3.00		3.00	
WBC: B	0-1 (%)	23/07/91	0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	323.00		320.00	
NA+	135-145 (MMOL/L)	23/07/91	146.00 >		146.00 >	
K+	3.5-5 (MMOL/L)	23/07/91	4.40		5.10 >	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.26		2.37	
PO4--	0.8-1.4 (MMOL/L)	23/07/91			0.72 <	
SGOT	3-40 (U/L)	23/07/91	17.00		21.00	
SGPT	9-40 (U/L)	23/07/91	19.00		15.00	
GAMMA GT	10-60 (U/L)	23/07/91	17.00		18.00	
LDH	80-210 (U/L)	23/07/91	170.00		157.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	192.00		202.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	5.60		5.60	
BUN	2.5-6.5 (MMOL/L)	23/07/91	3.60		4.10	
CREATININE	50-110 (UMOL/L)	23/07/91	108.00		116.00 >	
URIC ACID	155-405 (UMOL/L)	23/07/91	248.00		238.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	15.00		18.00 >	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	3.00		3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	69.00		69.00	
ALBUMINE	38-50 (G/L)	23/07/91	46.00		48.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	5.30		6.20	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	2.60 >>		2.60 >>	
TSH	0.4-4 (MU/L)	23/07/91	3.00			
T4	8.5-19 (PMOL/L)	23/07/91	12.50			

1919

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 327 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			23/01/92
			value (⊕)
Laboratory test	Range value	Range date	
HB	13-18 (G/DL)	23/07/91	15.50
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.83
WBC	4-11 (10 ⁹ /L)	23/07/91	7.80
WBC: N	40-75 (%)	23/07/91	58.00
WBC: L	20-45 (%)	23/07/91	37.00
WBC: E	1-6 (%)	23/07/91	0.00 <
WBC: M	2-10 (%)	23/07/91	5.00
WBC: B	0-1 (%)	23/07/91	0.00
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	222.00
NA+	135-145 (MMOL/L)	23/07/91	139.00
K+	3.5-5 (MMOL/L)	23/07/91	4.50
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.31
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.26
SGOT	3-40 (U/L)	23/07/91	16.00
SGPT	9-40 (U/L)	23/07/91	17.00
GAMMA GT	10-60 (U/L)	23/07/91	21.00
LDH	80-210 (U/L)	23/07/91	112.00
ALK. PHOSPH.	100-275 (U/L)	23/07/91	168.00
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	4.60
BUN	2.5-6.5 (MMOL/L)	23/07/91	4.60
CREATININE	50-110 (UMOL/L)	23/07/91	94.00
URIC ACID	155-405 (UMOL/L)	23/07/91	228.00
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	15.00
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	4.00
TOT. PROTEINS	56-85 (G/L)	23/07/91	74.00
ALBUMINE	38-50 (G/L)	23/07/91	54.00 >
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	5.10
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	1.30
TSH	0.4-4 (MU/L)	23/07/91	2.20
T4	8.5-19 (PMOL/L)	23/07/91	18.20

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1920

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 328 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			28/01/92
			value (c)
Laboratory test	Range value	Range date	
HB	13-18 (G/DL)	23/07/91	13.00
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.29 <
WBC	4-11 (10 ⁹ /L)	23/07/91	5.10
WBC: N	40-75 (%)	23/07/91	69.00
WBC: L	20-45 (%)	23/07/91	29.00
WBC: E	1-6 (%)	23/07/91	1.00
WBC: M	2-10 (%)	23/07/91	1.00 <
WBC: B	0-1 (%)	23/07/91	0.00
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	312.00
NA+	135-145 (MMOL/L)	23/07/91	141.00
K+	3.5-5 (MMOL/L)	23/07/91	4.40
Ca ⁺⁺	2.1-2.6 (MMOL/L)	23/07/91	2.18
PO ₄ ⁻⁻	0.8-1.4 (MMOL/L)	23/07/91	1.34
SGOT	3-40 (U/L)	23/07/91	19.00
SGPT	9-40 (U/L)	23/07/91	13.00
GAMMA GT	10-60 (U/L)	23/07/91	7.00 <
LDH	80-210 (U/L)	23/07/91	143.00
ALK. PHOSPH.	100-275 (U/L)	23/07/91	113.00
BUN	2.5-6.5 (MMOL/L)	23/07/91	6.10
CREATININE	50-110 (UMOL/L)	23/07/91	78.00
URIC ACID	155-405 (UMOL/L)	23/07/91	178.00
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	8.00
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	3.00
ALBUMINE	38-50 (G/L)	23/07/91	48.00
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	3.80
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	0.70 <
TSH	0.4-4 (MU/L)	23/07/91	15.00 >>
T4	8.5-19 (PMOL/L)	23/07/91	7.70 <

1001

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 11 Patient: 329 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/04/92		30/04/92		21/05/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	13.60		13.70		13.00	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.56		4.63		4.55	
WBC	4-11 (10 ⁹ /L)	23/07/91	5.30		5.50		6.80	
WBC: N	40-75 (%)	23/07/91	76.00	>	63.00			
WBC: L	20-45 (%)	23/07/91	22.00		34.00		34.90	
WBC: E	1-6 (%)	23/07/91	1.00		1.00			
WBC: M	2-10 (%)	23/07/91	1.00	<	2.00		8.90	
WBC: B	0-1 (%)	23/07/91	0.00		0.00			
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	255.00		246.00		318.00	
NA+	135-145 (MMOL/L)	23/07/91	144.00		139.00		134.00 <	
K+	3.5-5 (MMOL/L)	23/07/91	4.20		4.40		4.40	
Ca ⁺⁺	2.1-2.6 (MMOL/L)	23/07/91	2.22		2.19		2.41	
PO ₄ ⁻⁻	0.8-1.4 (MMOL/L)	23/07/91	1.09		1.18		1.32	
SGOT	3-40 (U/L)	23/07/91	17.00		15.00		14.00	
SGPT	9-40 (U/L)	23/07/91			22.00			
GAMMA GT	10-60 (U/L)	23/07/91	37.00		24.00		29.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	131.00		129.00		120.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	6.40		5.00		4.60	
BUN	2.5-6.5 (MMOL/L)	23/07/91	6.50		5.70		4.80	
CREATININE	50-110 (UMOL/L)	23/07/91	86.00		80.00		77.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	303.00		276.00		275.00	
TOT. BILIRUBIN	2-17 (UMOL/L)	23/07/91	4.00		6.00		9.00	
DIR. BILIRUBIN	0-5 (UMOL/L)	23/07/91	2.00		4.00		3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	79.00		79.00		73.00	
ALBUMINE	38-50 (G/L)	23/07/91	45.00		46.00		45.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	6.70		5.80		6.40	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	3.40	>>	2.80	>>	4.20 >>	
TSH	0.4-4 (MU/L)	23/07/91	1.50					
T4	8.5-19 (PMOL/L)	23/07/91	17.40					

1922

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 330 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/04/92		30/04/92		21/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HE	13-18 (G/DL)	23/07/91	15.70		16.90		15.70	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	5.26		5.36		4.95	
HBC	4-11 (10 ⁹ /L)	23/07/91	9.30		4.70		5.40	
HBC: N	40-75 (X)	23/07/91	85.00 >		84.00 >		90.00 >	
HBC: L	20-45 (X)	23/07/91	15.00 <		14.00 <		9.00 <<	
HBC: E	1-6 (X)	23/07/91	0.00 <		2.00 <		0.00 <	
HBC: M	2-10 (X)	23/07/91	0.00 <		0.00 <		1.00 <	
HBC: B	0-1 (X)	23/07/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	267.00		282.00		319.00	
NA+	135-145 (MMOL/L)	23/07/91	144.00				142.00	
K+	3.5-5 (MMOL/L)	23/07/91	4.90				4.50	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.34				2.28	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.73 >>				1.06	
SGOT	3-40 (U/L)	23/07/91	20.00				85.00 >>	
SGPT	9-40 (U/L)	23/07/91					77.00 >	
GAMMA GT	10-60 (U/L)	23/07/91	11.00				11.00	
LDH	80-210 (U/L)	23/07/91					196.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	156.00				155.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	4.20				3.80	
BUN	2.5-6.5 (MMOL/L)	23/07/91	5.20				5.00	
CREATININE	50-110 (UMOL/L)	23/07/91	108.00				93.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	397.00				325.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	14.00				12.00	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	4.40				3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	69.00				68.00	
ALBUMINE	38-50 (G/L)	23/07/91	44.00				43.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	4.90				4.90	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	1.00				1.50	
TSH	0.4-4 (MU/L)	23/07/91	2.20				1.90	
T4	8.5-19 (PMOL/L)	23/07/91	14.00					

1923

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 331 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/04/92		07/05/92		28/05/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	14.20		15.50		14.70	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.84				5.09	
WBC	4-11 (10 ⁹ /L)	23/07/91	4.90		4.00		4.70	
WBC: N	40-75 (%)	23/07/91	66.00				71.00	
WBC: L	20-45 (%)	23/07/91	29.00				27.00	
WBC: E	1-6 (%)	23/07/91	0.00	<			1.00	
WBC: M	2-10 (%)	23/07/91	5.00				1.00	
WBC: B	0-1 (%)	23/07/91	0.00				<	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	268.00		254.00		296.00	
NA+	135-145 (MMOL/L)	23/07/91	141.00		140.00		138.00	
K+	3.5-5 (MMOL/L)	23/07/91	4.30		4.10		4.30	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.27		2.46		2.51	
PQ4--	0.8-1.4 (MMOL/L)	23/07/91					0.92	
SGOT	3-40 (U/L)	23/07/91	41.00	>	38.00		23.00	
SGPT	9-40 (U/L)	23/07/91			74.00	>>	28.00	
GAMMA GT	10-60 (U/L)	23/07/91	141.00	>>	160.00	>>	85.00	
LDH	80-210 (U/L)	23/07/91	139.00		135.00		120.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	196.00		215.00		197.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	6.10		5.80		5.10	
BUN	2.5-6.5 (MMOL/L)	23/07/91	5.00		7.60	>	5.60	
CREATININE	50-110 (UMOL/L)	23/07/91	97.00		111.00	>	95.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	272.00		356.00		260.00	
TOT. BILIRUBIN	2-17 (UMOL/L)	23/07/91	6.00		9.00		8.00	
DIR. BILIRUBIN	0-5 (UMOL/L)	23/07/91			5.00		3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	81.00		84.00		80.00	
ALBUMINE	38-50 (G/L)	23/07/91	46.00		49.00		47.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	6.10		7.40	>	6.70	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	1.90		1.70		1.90	
TSH	0.4-4 (MU/L)	23/07/91	0.50					
T4	8.5-19 (PMOL/L)	23/07/91	12.50					

1924

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 332 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/05/92		08/06/92		29/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	16.70		16.00		15.50	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	5.16		5.04		4.96	
WBC	4-11 (10 ⁹ /L)	23/07/91	7.30		6.40		7.50	
WBC: N	40-75 (%)	23/07/91	95.00	>			76.20 >	
WBC: L	20-45 (%)	23/07/91	3.00	<<			17.80 <	
WBC: E	1-6 (%)	23/07/91	0.00	<			0.00 <	
WBC: M	2-10 (%)	23/07/91	2.00				6.00	
WBC: B	0-1 (%)	23/07/91	0.00				0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	289.00		274.00		277.00	
NA+	135-145 (MMOL/L)	23/07/91	145.00		148.00	>	143.00	
K+	3.5-5 (MMOL/L)	23/07/91	3.30	<	3.80		3.40 <	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.42		2.22		2.41	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	0.94		0.84		0.87	
SGOT	3-40 (U/L)	23/07/91	16.00		25.00		22.00	
SGPT	9-40 (U/L)	23/07/91	17.00		17.00		24.00	
GAMMA GT	10-60 (U/L)	23/07/91	29.00		28.00		27.00	
LDH	80-210 (U/L)	23/07/91	180.00		190.00		217.00 >	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	131.00		145.00		156.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	5.10		5.70		6.10	
BUN	2.5-6.5 (MMOL/L)	23/07/91	6.10		6.20			
CREATININE	50-110 (UMOL/L)	23/07/91	154.00	>	159.00	>	147.00 >	
URIC ACID	155-405 (UMOL/L)	23/07/91	430.00	>	427.00	>		
TOT. BILIRUBIN	2-17 (UMOL/L)	23/07/91	7.00		9.00		8.00	
DIR. BILIRUBIN	0-5 (UMOL/L)	23/07/91	2.00		3.00		3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	76.00		71.00		78.00	
ALBUMINE	38-50 (G/L)	23/07/91	42.00		41.00		43.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	5.80		5.50		6.40	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	1.20		1.60		1.30	
TSH	0.4-4 (MU/L)	23/07/91	0.60					

1925

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 333 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/05/92		16/06/92		07/07/92	
			value	(°)	value	(°)	value	(°)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	15.40		14.60		15.40	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	5.18		4.82		5.08	
HBC	4-11 (10 ⁹ /L)	23/07/91	5.90		6.30		7.60	
HBC: N	40-75 (%)	23/07/91	76.00	>	71.90		67.00	
HBC: L	20-45 (%)	23/07/91	22.00		25.80		28.00	
HBC: E	1-6 (%)	23/07/91	1.00		0.00	<	0.00	
HBC: M	2-10 (%)	23/07/91	0.00	<	2.30		4.00	
HBC: B	0-1 (%)	23/07/91	1.00		0.00		1.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	341.00		216.00		352.00	
NA+	135-145 (MMOL/L)	23/07/91	142.00		141.00		145.00	
K+	3.5-5 (MMOL/L)	23/07/91	4.20		3.90		4.80	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.38		2.26		2.30	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	0.86		0.76	<	1.10	
SGOT	3-40 (U/L)	23/07/91			35.00		34.00	
SGPT	9-40 (U/L)	23/07/91	24.00		28.00		24.00	
GAMMA GT	10-60 (U/L)	23/07/91	63.00	>	57.00		74.00	
LDH	80-210 (U/L)	23/07/91			214.00	>	153.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	186.00		186.00		206.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	4.80		6.00		4.70	
BUN	2.5-6.5 (MMOL/L)	23/07/91	4.00		5.60		5.70	
CREATININE	50-110 (UMOL/L)	23/07/91	100.00		98.00		103.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	436.00	>	446.00	>	453.00	
TOT. BILIRUBIN	2-17 (UMOL/L)	23/07/91	15.00		12.00		8.00	
DIR. BILIRUBIN	0-5 (UMOL/L)	23/07/91	3.00		1.00		2.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	75.00		70.00		71.00	
ALBUMINE	38-50 (G/L)	23/07/91	46.00		44.00		41.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	5.80		6.00		6.40	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	1.50		2.30	>	2.40	
TSH	0.4-4 (MU/L)	23/07/91	0.30	<<				

(°) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 334 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			21/05/92
			value (c)
Laboratory test	Range value	Range date	
HB	13-18 (g/dL)	23/07/91	13.40
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.86
WBC	4-11 (10 ⁹ /L)	23/07/91	4.60
WBC: N	40-75 (%)	23/07/91	77.00 >
WBC: L	20-45 (%)	23/07/91	20.00
WBC: E	1-6 (%)	23/07/91	1.00
WBC: M	2-10 (%)	23/07/91	2.00
WBC: B	0-1 (%)	23/07/91	0.00
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	367.00
NA+	135-145 (MMOL/L)	23/07/91	140.00
K+	3.5-5 (MMOL/L)	23/07/91	5.40 >
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.28
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.10
SGOT	3-40 (U/L)	23/07/91	10.00
SGPT	9-40 (U/L)	23/07/91	16.00
GAMMA GT	10-60 (U/L)	23/07/91	10.00
LDH	80-210 (U/L)	23/07/91	86.00
ALK. PHOSPH.	100-275 (U/L)	23/07/91	130.00
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	5.70
BUN	2.5-6.5 (MMOL/L)	23/07/91	4.30
CREATININE	50-110 (UMOL/L)	23/07/91	72.00
URIC ACID	155-405 (UMOL/L)	23/07/91	226.00
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	11.00
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	3.00
TOT. PROTEINS	56-85 (g/L)	23/07/91	69.00
ALBUMINE	38-50 (g/L)	23/07/91	44.00
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	5.10
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	0.50 <
TSH	0.4-4 (MU/L)	23/07/91	1.10

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(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 335 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/05/92		23/06/92		14/07/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	23/07/91	16.70		15.80		16.00	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	5.44		5.37		5.34	
HBC	4-11 (10 ⁹ /L)	23/07/91	5.30		5.60		7.50	
HBC: N	40-75 (%)	23/07/91	57.00		56.30		59.80	
HBC: L	20-45 (%)	23/07/91	43.00		37.00		36.10	
HBC: E	1-6 (%)	23/07/91	0.00	<	0.00	<	0.00	<
HBC: H	2-10 (%)	23/07/91	0.00	<	6.70		4.10	
HBC: B	0-1 (%)	23/07/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	369.00		295.00		334.00	
NA+	135-145 (MMOL/L)	23/07/91	140.00		141.00		136.00	
K+	3.5-5 (MMOL/L)	23/07/91	4.40		4.30		4.30	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.49		2.45		2.40	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	1.14		1.19		1.18	
SGOT	3-40 (U/L)	23/07/91			14.00		17.00	
SGPT	9-40 (U/L)	23/07/91	16.00		14.00		26.00	
GAMMA GT	10-60 (U/L)	23/07/91	25.00		17.00		22.00	
LDH	80-210 (U/L)	23/07/91			91.00		115.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	172.00		151.00		175.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	4.60		5.30		4.70	
BUN	2.5-6.5 (MMOL/L)	23/07/91	6.40		7.30	>	6.20	
CREATININE	50-110 (UMOL/L)	23/07/91	108.00		107.00		105.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	378.00		421.00	>	392.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	8.00		10.00		9.00	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	2.00		3.00		3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	82.00		74.00		77.00	
ALBUMINE	38-50 (G/L)	23/07/91	47.00		47.00		45.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	7.20	>	6.00		6.60	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	6.50	>>	3.60	>>	6.90	>>
TSH	0.4-4 (MU/L)	23/07/91	0.90					

1928

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 11 Patient: 336 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	
			15/06/92	
			value	(*)
Laboratory test	Range value	Range date		
HB	13-18 (G/DL)	23/07/91	13.10	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.48	<
HBC	4-11 (10 ⁹ /L)	23/07/91	10.80	
HBC: N	40-75 (%)	23/07/91	81.00	>
HBC: L	20-45 (%)	23/07/91	11.00	<<
HBC: E	1-6 (%)	23/07/91	1.00	
HBC: M	2-10 (%)	23/07/91	1.00	<
HBC: B	0-1 (%)	23/07/91	0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	432.00	>
NA+	135-145 (MMOL/L)	23/07/91	137.00	
K+	3.5-5 (MMOL/L)	23/07/91	3.70	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.45	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	0.89	
SGOT	3-40 (U/L)	23/07/91	13.00	
SGPT	9-40 (U/L)	23/07/91	25.00	
GAMMA GT	10-60 (U/L)	23/07/91	32.00	
LDH	80-210 (U/L)	23/07/91	147.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	164.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	3.40	<
BUN	2.5-6.5 (MMOL/L)	23/07/91	6.10	
CREATININE	50-110 (UMOL/L)	23/07/91	71.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	413.00	>
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	5.00	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	2.00	
ALBUMINE	38-50 (G/L)	23/07/91	42.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	6.40	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	3.90	>>
TSH	0.4-4 (MU/L)	23/07/91	2.60	

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(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done (*) missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 337 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/06/92		23/07/92		13/08/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	18-18 (G/DL)	23/07/91	12.50	<	12.90	<	13.50	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	3.97	<	4.04	<	4.17 <	
WBC	4-11 (10 ⁹ /L)	23/07/91	6.10		6.70		7.30	
WBC: N	40-75 (%)	23/07/91	82.00	>			66.00	
WBC: L	20-45 (%)	23/07/91	14.00	<			22.00	
WBC: E	1-6 (%)	23/07/91	1.00				3.00	
WBC: M	2-10 (%)	23/07/91	3.00				7.00	
WBC: B	0-1 (%)	23/07/91	0.00				2.00 >>	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	179.00		173.00		189.00	
NA+	135-145 (MMOL/L)	23/07/91	142.00		140.00		143.00	
K+	3.5-5 (MMOL/L)	23/07/91	4.20		4.80		4.50	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.27		2.30		2.21	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	0.98		1.32			
SGOT	3-40 (U/L)	23/07/91	20.00		15.00		23.00	
SGPT	9-40 (U/L)	23/07/91	27.00		22.00		15.00	
GAMMA GT	10-60 (U/L)	23/07/91	16.00		15.00		15.00	
LDH	80-210 (U/L)	23/07/91	127.00		121.00		113.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	108.00		117.00		127.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	3.30	<	4.50		4.60	
BUN	2.5-6.5 (MMOL/L)	23/07/91	6.20		5.00		4.60	
CREATININE	50-110 (UMOL/L)	23/07/91	82.00		85.00		79.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	183.00		196.00		162.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	9.00		7.00		7.00	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	3.00		2.00			
TOT. PROTEINS	56-86 (G/L)	23/07/91	69.00		72.00		72.00	
ALBUMINE	38-50 (G/L)	23/07/91	43.00		45.00		44.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	5.00		4.60		4.70	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	0.40	<	0.40	<	0.40 <	
TSH	0.4-4 (MU/L)	23/07/91	0.40				0.60	
T4	8.5-19 (PMOL/L)	23/07/91	14.00				14.90	

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(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 11 Patient: 338 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date	
			Screen	
			14/07/92	
			value	(€)
Laboratory test	Range value	Range date		
HB	13-18 (G/DL)	23/07/91	14.10	
RBC	4.5-6.5 (10 ¹² /L)	23/07/91	4.43	<
HBC	4-11 (10 ⁹ /L)	23/07/91	6.60	
HBC: N	40-75 (%)	23/07/91	65.00	
HBC: L	20-45 (%)	23/07/91	34.00	
HBC: E	1-6 (%)	23/07/91	0.00	<
HBC: M	2-10 (%)	23/07/91	1.00	<
HBC: B	0-1 (%)	23/07/91	0.00	
PLATELETS	150-400 (10 ⁹ /L)	23/07/91	155.00	
NA+	135-145 (MMOL/L)	23/07/91	138.00	
K+	3.5-5 (MMOL/L)	23/07/91	4.00	
Ca++	2.1-2.6 (MMOL/L)	23/07/91	2.21	
PO4--	0.8-1.4 (MMOL/L)	23/07/91	0.79	<
SGOT	3-40 (U/L)	23/07/91	18.00	
SGPT	9-40 (U/L)	23/07/91	14.00	
GAMMA GT	10-60 (U/L)	23/07/91	17.00	
LDH	80-210 (U/L)	23/07/91	128.00	
ALK. PHOSPH.	100-275 (U/L)	23/07/91	151.00	
GLUCOSE	3.5-8 (MMOL/L)	23/07/91	6.20	
BUN	2.5-6.5 (MMOL/L)	23/07/91	2.60	
CREATININE	50-110 (UMOL/L)	23/07/91	87.00	
URIC ACID	155-405 (UMOL/L)	23/07/91	297.00	
TOT BILIRUBIN	2-17 (UMOL/L)	23/07/91	12.00	
DIR BILIRUBIN	0-5 (UMOL/L)	23/07/91	3.00	
TOT. PROTEINS	56-85 (G/L)	23/07/91	66.00	
ALBUMINE	38-50 (G/L)	23/07/91	43.00	
TOT. CHOLEST.	3.5-6.7 (MMOL/L)	23/07/91	4.10	
TRIGLYCERIDES	0.8-1.9 (MMOL/L)	23/07/91	0.70	<
TSH	0.4-4 (MU/L)	23/07/91	1.50	

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(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 12 Patient: 367 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/12/91		10/01/92		31/01/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	120-150 (G/L)	15/12/91	158.00	>	139.00		143.00	
HT	0.37-0.43 (L/L)	15/12/91	0.45	>	0.42		0.42	
RBC	4-4.5 (10 ¹² /L)	15/12/91	4.97	>	4.60	>	4.64	
HBC	4.5-10.5 (10 ⁹ /L)	15/12/91	9.20		5.10		6.10	
HBC: N	65-72 (%)	15/12/91	46.00	<	71.00		68.00	
HBC: L	20-35 (%)	15/12/91	32.00		24.00		23.00	
HBC: E	1-3 (%)	15/12/91	0.00	<	1.00		3.00	
HBC: M	3-7 (%)	15/12/91	2.00	<	4.00		5.00	
HBC: B	0-1 (%)	15/12/91	0.00		0.00		1.00	
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	317.00		315.00		365.00	
NA+	135-145 (MMOL/L)	15/12/91	142.00		139.00		139.00	
K+	3.5-5 (MMOL/L)	15/12/91	4.00		3.80		4.10	
CL-	98-108 (MMOL/L)	15/12/91	100.00		102.00		104.00	
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.55		2.45		2.30	
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.27		1.25		1.12	
SGOT	10-42 (IU/L)	15/12/91	24.00		21.00		46.00	
SGPT	10-60 (IU/L)	15/12/91	20.00		19.00		63.00	
GAMMA GT	7-64 (IU/L)	15/12/91	22.00		20.00		74.00	
LDH	91-180 (IU/L)	15/12/91	180.00		157.00		177.00	
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	68.00		66.00		102.00	
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	5.70		4.40		5.40	
BUN	2.5-6.4 (MMOL/L)	15/12/91	5.50		6.90	>	6.60	
CREATININE	53-115 (UMOL/L)	15/12/91	70.00		65.00		70.00	
URIC ACID	155-428 (UMOL/L)	15/12/91	274.00		305.00		338.00	
TOT BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	16.20		10.80		11.80	
DIR BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	0.00		0.00		0.80	
TOT. PROTEINS	60-83 (G/L)	15/12/91	73.00		65.00		68.00	
ALBUMINE	32-55 (G/L)	15/12/91	41.90		39.20		37.00	
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	5.69		5.80		6.57	
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	1.10		1.42		2.00	
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.04		0.04		0.04	
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.09		0.09		0.08	
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.13		0.13		0.13	
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.12		0.11	<	0.13	
TSH	0.5-4 (MU/L)	15/12/91	3.70					
T4	64-167 (NMOL/L)	15/12/91	116.00					

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(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range).
 ** missing laboratory test value nd laboratory not done () missing range value

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 12 Patient: 368 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			19/12/91		14/01/92		04/02/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	120-150 (G/L)	15/12/91	134.00		144.00		137.00	
HT	0.37-0.43 (L/L)	15/12/91	0.40		0.42		0.41	
RBC	4-4.5 (10 ¹² /L)	15/12/91	4.44		4.74 >		4.55 >	
WBC	4.5-10.5 (10 ⁹ /L)	15/12/91	9.00		7.90		6.70	
WBC: N	65-72 (%)	15/12/91	78.00 >		72.00		77.00 >	
WBC: L	20-35 (%)	15/12/91	18.00 <		25.00		20.00	
WBC: E	1-3 (%)	15/12/91	1.00		1.00		1.00	
WBC: M	3-7 (%)	15/12/91	3.00		2.00 <		2.00 <	
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	295.00		356.00		304.00	
NA+	135-145 (MMOL/L)	15/12/91	136.00		137.00		139.00	
K+	3.5-5 (MMOL/L)	15/12/91	4.60		4.60		4.30	
CL-	98-108 (MMOL/L)	15/12/91	101.00		102.00		104.00	
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.57 >		2.53		2.49	
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.16		1.27		1.43	
SGOT	10-42 (IU/L)	15/12/91	17.00		18.00		17.00	
SGPT	10-60 (IU/L)	15/12/91	25.00		21.00		17.00	
GAMMA GT	7-64 (IU/L)	15/12/91	23.00		21.00		17.00	
LDH	91-180 (IU/L)	15/12/91	133.00		137.00		112.00	
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	92.00		86.00		89.00	
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	5.60		5.40		5.40	
BUN	2.5-6.4 (MMOL/L)	15/12/91	2.90		4.10		4.60	
CREATININE	53-115 (UMOL/L)	15/12/91	66.00		74.00		67.00	
URIC ACID	155-428 (UMOL/L)	15/12/91	372.00		304.00		335.00	
TOT. BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	8.40		9.70		8.30	
DIR. BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	0.00		0.60		0.60	
TOT. PROTEINS	60-83 (G/L)	15/12/91	84.00 >		76.00		74.00	
ALBUMINE	32-55 (G/L)	15/12/91	36.80		40.60		38.20	
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	5.84		5.14		5.37	
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	1.78		2.60 >>		2.12 >	
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.03		0.03		0.03	
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.12		0.08		0.08	
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.17 >		0.15		0.15	
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.15		0.16		0.16	
TSH	0.5-4 (MU/L)	15/12/91	2.20					
T4	64-167 (NMOL/L)	15/12/91	83.00					

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(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 12 Patient: 369 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			22/04/92	13/05/92
			value (†)	value (‡)
Laboratory test	Range value	Range date		
HB	120-150 (G/L)	15/12/91	130.00	130.00
HT	0.37-0.43 (L/L)	15/12/91	0.40	0.39
RBC	4-4.5 (10 ¹² /L)	15/12/91	4.32	4.29
WBC	4.5-10.5 (10 ⁹ /L)	15/12/91	7.00	6.40
WBC: N	65-72 (%)	15/12/91	85.00	81.00
WBC: L	20-35 (%)	15/12/91	12.00	18.00
WBC: E	1-3 (%)	15/12/91	2.00	0.00
WBC: M	3-7 (%)	15/12/91	3.00	1.00
WBC: B	0-1 (%)	15/12/91	0.00	0.00
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	352.00	352.00
NA+	135-145 (MMOL/L)	15/12/91	139.00	136.00
K+	3.5-5 (MMOL/L)	15/12/91	4.40	5.20
CL-	98-108 (MMOL/L)	15/12/91	101.00	105.00
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.38	2.42
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.15	1.41
SGOT	10-42 (IU/L)	15/12/91	26.00	33.00
SGPT	10-60 (IU/L)	15/12/91	28.00	38.00
GAMMA GT	7-64 (IU/L)	15/12/91	11.00	7.00
LDH	91-180 (IU/L)	15/12/91	143.00	285.00
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	73.00	76.00
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	5.40	5.20
BUN	2.5-6.4 (MMOL/L)	15/12/91	4.00	6.10
CREATININE	53-115 (UMOL/L)	15/12/91	68.00	72.00
URIC ACID	155-428 (UMOL/L)	15/12/91	226.00	257.00
TOT BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	8.00	24.20
DIR BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	1.20	5.50
TOT. PROTEINS	60-83 (G/L)	15/12/91	70.00	69.00
ALBUMINE	32-55 (G/L)	15/12/91	40.40	40.30
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	6.86	5.93
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	1.35	1.53
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.06	0.03
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.08	0.12
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.15	0.15
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.11	0.11
TSH	0.5-4 (MU/L)	15/12/91	0.50	
T4	64-167 (NMOL/L)	15/12/91	89.00	

1934

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 12 Patient: 370 Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			27/04/92		19/05/92	
			value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date				
HB	140-160 (G/L)	15/12/91	152.00		150.00	
HT	0.42-0.5 (L/L)	15/12/91	0.44		0.44	
RBC	4.5-5 (10 ¹² /L)	15/12/91	4.97		5.03	>
WBC	4.5-10 (10 ⁹ /L)	15/12/91	9.00		7.80	>
WBC: N	65-72 (%)	15/12/91	64.00	<	59.00	<
WBC: L	20-35 (%)	15/12/91	31.00		37.00	>
WBC: E	1-3 (%)	15/12/91	1.00		1.00	
WBC: M	3-7 (%)	15/12/91	2.00	<	3.00	<
WBC: B	0-1 (%)	15/12/91	2.00	>>	0.00	>>
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	293.00		301.00	
NA+	135-145 (MMOL/L)	15/12/91	146.00	>	140.00	>
K+	3.5-5 (MMOL/L)	15/12/91	4.20		4.50	
CL-	98-108 (MMOL/L)	15/12/91	108.00		102.00	>
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.51		2.55	
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.09		1.06	
SGOT	10-42 (IU/L)	15/12/91	23.00		22.00	
SGPT	10-60 (IU/L)	15/12/91	22.00		37.00	>
GAMMA GT	7-64 (IU/L)	15/12/91	33.00		30.00	
LDH	91-180 (IU/L)	15/12/91	114.00		114.00	
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	98.00		83.00	>
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	6.50	>	6.10	>
BUN	2.5-6.4 (MMOL/L)	15/12/91	10.10	>>	5.80	>>
CREATININE	53-115 (UMOL/L)	15/12/91	108.00		125.00	>
URIC ACID	155-428 (UMOL/L)	15/12/91	399.00		487.00	>
TOT BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	14.00		14.00	
DIR BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	1.10		0.00	>
TOT. PROTEINS	60-83 (G/L)	15/12/91	71.00		66.00	>
ALBUMINE	32-55 (G/L)	15/12/91	41.10		42.30	
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	6.11		6.35	
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	2.23	>	2.15	>
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.02	<<	0.03	<<
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.07		0.07	
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.13		0.13	
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.13		0.13	
TSH	0.5-4 (MU/L)	15/12/91	0.40	<<		<<
T4	64-167 (NMOL/L)	15/12/91	84.00			

1935

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 12 Patient: 371 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 7	
			21/04/92		08/05/92	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	120-150 (G/L)	15/12/91	143.00		124.00	
HT	0.37-0.43 (L/L)	15/12/91	0.42		0.37	
RBC	4-4.5 (10 ¹² /L)	15/12/91	4.51	>	4.07	
WBC	4.5-10.5 (10 ⁹ /L)	15/12/91	9.60		7.30	
WBC: N	65-72 (%)	15/12/91	56.00	<	56.00	
WBC: L	20-35 (%)	15/12/91	39.00	>	39.00	
WBC: E	1-3 (%)	15/12/91	3.00		2.00	
WBC: M	3-7 (%)	15/12/91	2.00	<	3.00	
WBC: B	0-1 (%)	15/12/91	0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	238.00		213.00	
NA+	135-145 (MMOL/L)	15/12/91	140.00		138.00	
K+	3.5-5 (MMOL/L)	15/12/91	4.20		4.10	
CL-	98-108 (MMOL/L)	15/12/91	100.00		105.00	
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.47		2.43	
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.24		1.34	
SGOT	10-42 (IU/L)	15/12/91	19.00		17.00	
SGPT	10-60 (IU/L)	15/12/91	13.00		12.00	
GAMMA GT	7-64 (IU/L)	15/12/91	17.00		17.00	
LDH	91-180 (IU/L)	15/12/91	142.00		131.00	
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	83.00		74.00	
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	4.60		4.60	
BUN	2.5-6.4 (MMOL/L)	15/12/91	4.40		4.70	
CREATININE	53-115 (UMOL/L)	15/12/91	77.00		81.00	
URIC ACID	155-428 (UMOL/L)	15/12/91	219.00		228.00	
TOT BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	8.70		8.30	
DIR BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	0.00		0.20	
TOT. PROTEINS	60-83 (G/L)	15/12/91	77.00		66.50	
ALBUMINE	32-55 (G/L)	15/12/91	39.20		36.30	
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	6.27		6.25	
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	1.81		2.05	
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.03			
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.09			
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.15			
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.17			
TSH	0.5-4 (MU/L)	15/12/91	0.90			
T4	64-167 (NMOL/L)	15/12/91	81.00			

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(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 12 Patient: 372 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/06/92		01/07/92		17/07/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	140-160 (G/L)	15/12/91	158.00		149.00		152.00	
HT	0.42-0.5 (L/L)	15/12/91	0.47		0.45		0.46	
RBC	4.5-5 (10 ¹² /L)	15/12/91	5.13 >		4.88		5.00	
WBC	4.5-10 (10 ⁹ /L)	15/12/91	4.90		4.90		4.70	
WBC: N	65-72 (%)	15/12/91	51.00 <		47.00 <		52.00 <	
WBC: L	20-35 (%)	15/12/91	47.00 >>		51.00 >>		45.00 >	
WBC: E	1-3 (%)	15/12/91	0.00 <		0.00 <		0.00 <	
WBC: M	3-7 (%)	15/12/91	2.00 <		2.00 <		3.00	
WBC: B	0-1 (%)	15/12/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	190.00		208.00		209.00	
NA+	135-145 (MMOL/L)	15/12/91	137.00		138.00		138.00	
K+	3.5-5 (MMOL/L)	15/12/91	4.50		4.00		4.40	
CL-	98-108 (MMOL/L)	15/12/91	101.00		102.00		102.00	
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.36		2.26		2.29	
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.08		1.25		0.92	
SGOT	10-42 (IU/L)	15/12/91	19.00		17.00		18.00	
SGPT	10-60 (IU/L)	15/12/91	13.00		12.00		12.00	
GAMMA GT	7-64 (IU/L)	15/12/91	16.00		12.00		12.00	
LDH	91-180 (IU/L)	15/12/91	142.00		127.00		126.00	
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	78.00		75.00		74.00	
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	5.30		5.00		4.70	
BUN	2.5-6.4 (MMOL/L)	15/12/91	4.90		4.10		5.20	
CREATININE	53-115 (UMOL/L)	15/12/91	113.00		114.00		108.00	
URIC ACID	155-428 (UMOL/L)	15/12/91	404.00		430.00 >		441.00 >	
TOT BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	10.60		15.80		17.10	
DIR BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	0.70		0.80		0.00	
TOT. PROTEINS	60-83 (G/L)	15/12/91	69.00		68.00		70.00	
ALBUMINE	32-55 (G/L)	15/12/91	38.00		36.40		37.90	
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	5.02		5.03		5.49	
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	1.57		1.07		1.05	
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.03		0.03		0.02 <<	
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.09		0.10		0.09	
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.15		0.12		0.13	
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.15		0.20		0.17	
TSH	0.5-4 (MU/L)	15/12/91	0.40	<<				
T4	64-167 (NMOL/L)	15/12/91	92.00					

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 12 Patient: 373 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/06/92		25/06/92		14/07/92	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	140-160 (G/L)	15/12/91	157.00		143.00		156.00	
HT	0.42-0.5 (L/L)	15/12/91	0.46		0.48		0.46	
RBC	4.5-5 (10 ¹² /L)	15/12/91	5.06 >		5.28 >		5.04 >	
HBC	4.5-10 (10 ⁹ /L)	15/12/91	7.70 >		8.30 >		12.10 >	
HBC: N	65-72 (%)	15/12/91	91.00 >		66.00 >		80.00 >	
HBC: L	20-35 (%)	15/12/91	7.00 <<		30.00		17.00 <	
HBC: E	1-3 (%)	15/12/91	1.00		1.00		1.00	
HBC: H	3-7 (%)	15/12/91	1.00 <		3.00		2.00 <	
HBC: B	0-1 (%)	15/12/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	338.00		346.00		336.00	
NA+	135-145 (MMOL/L)	15/12/91	139.00		138.00		136.00	
K+	3.5-5 (MMOL/L)	15/12/91	4.10		5.20 >		4.60	
CL-	98-108 (MMOL/L)	15/12/91	105.00		102.00		102.00	
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.43		2.72 >		2.35	
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.13		1.40		1.08	
SGOT	10-42 (IU/L)	15/12/91	24.00		28.00		28.00	
SGPT	10-60 (IU/L)	15/12/91	20.00		26.00		21.00	
GAMMA GT	7-64 (IU/L)	15/12/91	18.00		22.00		13.00	
LDH	91-180 (IU/L)	15/12/91	119.00		149.00		151.00	
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	78.00		123.00 >		88.00	
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	4.60		5.70		5.00	
BUN	2.5-6.4 (MMOL/L)	15/12/91	6.80 >		6.60 >		6.00	
CREATININE	53-115 (UMOL/L)	15/12/91	98.00		97.00		85.00	
URIC ACID	155-428 (UMOL/L)	15/12/91	258.00		258.00		209.00	
TOT. BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	9.00		11.60		10.90	
DIR. BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	0.00		1.40		0.20	
TOT. PROTEINS	60-83 (G/L)	15/12/91	66.00		77.00		73.00	
ALBUMINE	32-55 (G/L)	15/12/91	40.00		45.80		42.00	
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	4.82		6.77		4.39	
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	1.74		1.78		1.53	
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.03		0.03		0.03	
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.08		0.12		0.08	
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.10		0.11		0.10	
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.21 >		0.15		0.14	
TSH	0.5-4 (MU/L)	15/12/91	0.60					
T4	64-167 (NMOL/L)	15/12/91	91.00					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 12 Patient: 374 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 28	
			09/06/92		30/06/92		06/07/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	120-150 (G/L)	15/12/91	130.00		133.00		138.00	
HT	0.37-0.43 (L/L)	15/12/91	0.39		0.40		0.42	
RBC	4-4.5 (10 ¹² /L)	15/12/91	4.40		4.56 >		4.73 >	
WBC	4.5-10.5 (10 ⁹ /L)	15/12/91	6.90		8.50		7.70	
WBC: N	65-72 (%)	15/12/91	62.00 <		66.00		69.00	
WBC: L	20-35 (%)	15/12/91	29.00		25.00		25.00	
WBC: E	1-3 (%)	15/12/91	4.00 >>		1.00		4.00 >>	
WBC: M	3-7 (%)	15/12/91	4.00		8.00 >		2.00 <	
WBC: B	0-1 (%)	15/12/91	1.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	409.00 >		302.00		321.00	
NA+	135-145 (MMOL/L)	15/12/91	141.00		139.00		140.00	
K+	3.5-5 (MMOL/L)	15/12/91	4.30		4.20		4.90	
CL-	98-108 (MMOL/L)	15/12/91	105.00		106.00		102.00	
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.51		2.39		2.43	
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.28		1.02		1.17	
SGOT	10-42 (IU/L)	15/12/91	20.00		20.00		19.00	
SGPT	10-60 (IU/L)	15/12/91	22.00		22.00		24.00	
GAMMA GT	7-64 (IU/L)	15/12/91	22.00		16.00		20.00	
LDH	91-180 (IU/L)	15/12/91	123.00		139.00		126.00	
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	74.00		70.00		77.00	
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	5.20		5.30		5.00	
BUN	2.5-6.4 (MMOL/L)	15/12/91	3.30		4.10		4.80	
CREATININE	53-115 (UMOL/L)	15/12/91	85.00		77.00		97.00	
URIC ACID	155-428 (UMOL/L)	15/12/91	285.00		345.00		361.00	
TOT BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	10.30		14.50		10.60	
DIR BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	0.70		0.00		0.00	
TOT. PROTEINS	60-83 (G/L)	15/12/91	71.00		70.00		72.00	
ALBUMINE	32-55 (G/L)	15/12/91	44.00		41.80		43.30	
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	5.67		5.07		5.14	
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	1.61		1.23		1.20	
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.03		0.04		0.04	
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.09		0.08		0.09	
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.15		0.12		0.15	
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.11 <		0.11 <		0.14	
TSH	0.5-4 (MU/L)	15/12/91	1.00					
T4	64-167 (NMOL/L)	15/12/91	159.00					

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 12 Patient: 375 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			12/06/92
			value (c)
Laboratory test	Range value	Range date	
HB	140-160 (G/L)	15/12/91	157.00
HT	0.42-0.5 (L/L)	15/12/91	0.47
RBC	4.5-5 (10 ¹² /L)	15/12/91	4.92
MBC	4.5-10 (10 ⁹ /L)	15/12/91	9.00
MBC: N	65-72 (%)	15/12/91	75.00 >
MBC: L	20-35 (%)	15/12/91	15.00 <
MBC: E	1-3 (%)	15/12/91	3.00
MBC: M	3-7 (%)	15/12/91	7.00
MBC: B	0-1 (%)	15/12/91	0.00
PLATELETS	150-400 (10 ⁹ /L)	15/12/91	223.00
NA+	135-145 (MMOL/L)	15/12/91	140.00
K+	3.5-5 (MMOL/L)	15/12/91	4.40
CL-	98-108 (MMOL/L)	15/12/91	105.00
Ca++	2.1-2.55 (MMOL/L)	15/12/91	2.39
PO4--	0.9-1.45 (MMOL/L)	15/12/91	1.32
SGOT	10-42 (IU/L)	15/12/91	17.00
SGPT	10-60 (IU/L)	15/12/91	17.00
GAMMA GT	7-64 (IU/L)	15/12/91	28.00
LDH	91-180 (IU/L)	15/12/91	127.00
ALK. PHOSPH.	42-121 (IU/L)	15/12/91	68.00
GLUCOSE	3.9-5.8 (MMOL/L)	15/12/91	4.10
BUN	2.5-6.4 (MMOL/L)	15/12/91	6.00
CREATININE	53-115 (UMOL/L)	15/12/91	83.00
URIC ACID	155-428 (UMOL/L)	15/12/91	316.00
TOT BILIRUBIN	3.4-17.1 (UMOL/L)	15/12/91	11.30
DIR BILIRUBIN	0-3.4 (UMOL/L)	15/12/91	1.20
TOT. PROTEINS	60-83 (G/L)	15/12/91	62.00
ALBUMINE	32-55 (G/L)	15/12/91	37.40
TOT. CHOLEST.	4.15-8 (MMOL/L)	15/12/91	6.03
TRIGLYCERIDES	0.4-1.92 (MMOL/L)	15/12/91	1.60
GLOBULINS ALPHA 1	0.03-0.06 ()	15/12/91	0.03
GLOBULINS ALPHA 2	0.07-0.12 ()	15/12/91	0.09
GLOBULINS BETA	0.09-0.15 ()	15/12/91	0.12
GLOBULINS GAMMA	0.12-0.2 ()	15/12/91	0.11 <
TSH	0.5-4 (MU/L)	15/12/91	0.40 <<
T4	64-167 (NNOL/L)	15/12/91	94.00

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 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 13 Patient: 13 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/04/91		02/05/91		24/05/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/04/91	15.40		16.00		16.40	
HT	42-54 (%)	01/04/91	45.30		47.00		48.20	
RBC	4-6 (10 ¹² /L)	01/04/91	5.35		5.53		5.69	
HBC	4-11 (10 ⁹ /L)	01/04/91	8.49		8.77		8.37	
HBC: N	2.27-7.68 (10 ⁹ /L)	01/04/91	4.53		4.40		4.62	
HBC: L	0.83-3.14 (10 ⁹ /L)	01/04/91	2.89		3.09		2.38	
HBC: E	0-0.49 (10 ⁹ /L)	01/04/91	0.49		0.58	>	0.51	
HBC: M	0.12-0.8 (10 ⁹ /L)	01/04/91	0.50		0.63	>	0.83	
HBC: B	0-0.16 (10 ⁹ /L)	01/04/91	0.08		0.07		0.03	
PLATELETS	150-350 (10 ⁹ /L)	01/04/91	282.00		285.00		311.00	
NA+	135-145 (MMOL/L)	01/04/91	136.00		140.00		141.00	
K+	3.5-5 (MMOL/L)	01/04/91	3.80		4.30		4.50	
CL-	95-105 (MMOL/L)	01/04/91	98.00					
Ca++	2.1-2.6 (MMOL/L)	01/04/91	2.41		2.34		2.44	
PO4--	0.6-1.4 (MMOL/L)	01/04/91	0.94		1.16		1.00	
SGOT	11-55 (U/L)	01/04/91	29.00		30.00		24.00	
GAMMA GT	5-80 (U/L)	01/04/91	12.00		7.00			
LDH	120-240 (U/L)	01/04/91					131.00	
ALK. PHOSPH.	35-110 (U/L)	01/04/91	60.00		71.00		81.00	
GLUCOSE	3.3-6.4 (MMOL/L)	01/04/91	4.90		5.30			
UREA	2.5-7.7 (MMOL/L)	01/04/91	5.60		5.30		4.00	
CREATININE	0.03-0.11 (MMOL/L)	01/04/91	0.07		0.10		0.09	
TOT. BILIRUBIN	3-18 (UMOL/L)	01/04/91	9.00		7.00		13.00	
DIR. BILIRUBIN	0-7 (UMOL/L)	01/04/91	4.00					
TOT. PROTEINS	61-84 (G/L)	01/04/91	67.00		71.00		73.00	
ALBUMINE	35-50 (G/L)	01/04/91	42.00		47.00		48.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	01/04/91	5.40		5.50		5.50	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/04/91	1.20		1.30		1.40	
GLOBULINS ALPHA 1	2-6 (G/L)	01/04/91	3.00		3.00		3.00	
GLOBULINS ALPHA 2	4-9 (G/L)	01/04/91	5.00		5.00		6.00	
GLOBULINS BETA	6-11 (G/L)	01/04/91	7.00		8.00		6.00	
GLOBULINS GAMMA	8-18 (G/L)	01/04/91	7.00	<	9.00		7.00	
TSH	0.15-3.5 (MU/L)	01/04/91	1.30					
T4	9.4-25 (NMOL/L)	01/04/91	17.50					

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1941

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 13 Patient: 14 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/07/91		24/07/91		15/08/91	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	03/04/91	15.10		15.70		14.90	
HT	40-54 (%)	03/04/91					43.40	
RBC	4.5-6.5 (10 ¹² /L)	03/04/91	5.76		5.97		5.62	
HBC	4-11 (10 ⁹ /L)	03/04/91	6.70		6.70		5.90	
HBC: N	2-8 (10 ⁹ /L)	03/04/91	4.20		4.00		3.10	
HBC: L	1-4 (10 ⁹ /L)	03/04/91	1.50		1.70		1.90	
HBC: E	0-0.6 (10 ⁹ /L)	03/04/91	0.60		0.60		0.60	
HBC: M	0-1 (10 ⁹ /L)	03/04/91	0.30		0.30		0.20	
HBC: B	0-0.2 (10 ⁹ /L)	03/04/91	0.10		0.10		0.10	
PLATELETS	150-450 (10 ⁹ /L)	03/04/91	319.00		306.00		318.00	
NA+	136-146 (MMOL/L)	03/04/91	139.00		139.00		142.00	
K+	3.5-5 (MMOL/L)	03/04/91	5.00		4.70		4.00	
CL-	95-110 (MMOL/L)	03/04/91	101.00		103.00		104.00	
Ca++	2.15-2.65 (MMOL/L)	03/04/91	2.33		2.32		2.22	
PO4--	0.8-1.4 (MMOL/L)	03/04/91	1.30		1.20		1.30	
SGOT	0-40 (U/L)	03/04/91	36.00		38.00		46.00	>
SGPT	0-40 (U/L)	03/04/91					15.00	
GAMMA GT	0-45 (U/L)	03/04/91	19.00		17.00			
LDH	250-520 (U/L)	03/04/91	295.00		275.00		259.00	
ALK. PHOSPH.	30-120 (U/L)	03/04/91	54.00		62.00		50.00	
GLUCOSE	4-5.5 (MMOL/L)	03/04/91	4.50		5.10		4.30	
UREA	2.3-7.6 (MMOL/L)	03/04/91	5.90		4.30		4.00	
CREATININE	0.05-0.11 (MMOL/L)	03/04/91	0.10		0.10		0.10	
URIC ACID	0.18-0.48 (MMOL/L)	03/04/91	0.22		0.18		0.18	
TOT BILIRUBIN	0-20 (UMOL/L)	03/04/91	13.00		13.00		8.00	
TOT. PROTEINS	60-80 (G/L)	03/04/91	84.00	>	82.00	>	78.00	
ALBUMINE	35-50 (G/L)	03/04/91	49.00		47.00		45.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	03/04/91	5.40		5.30		5.00	
TRIGLYCERIDES	0.5-2 (MMOL/L)	03/04/91	1.40		1.30		2.30	>
TSH	0.5-4 (MIU/L)	03/04/91	3.60					

1942

(ϕ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 13 Patient: 15 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/07/91		25/07/91		15/08/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	12.00	<	12.50	<	13.20	
HT	42-54 (X)	01/06/91	37.30	<	38.50	<	40.10 <	
RBC	4-6 (10 ¹² /L)	01/06/91	4.12		4.39		4.58	
HBC	4-11 (10 ⁹ /L)	01/06/91	10.96		8.41		9.30	
HBC: N	2.27-7.68 (10 ⁹ /L)	01/06/91	4.44		4.46		4.75	
HBC: L	0.83-3.14 (10 ⁹ /L)	01/06/91	3.96	>	3.19	>	3.87 >	
HBC: E	0-0.49 (10 ⁹ /L)	01/06/91	0.32		0.38		0.36	
HBC: M	0.12-0.8 (10 ⁹ /L)	01/06/91	1.10	>>	0.37		0.26	
HBC: B	0-0.16 (10 ⁹ /L)	01/06/91	0.00				0.06	
PLATELETS	150-350 (10 ⁹ /L)	01/06/91			263.00		262.00	
NA+	135-145 (MMOL/L)	01/06/91	135.00		141.00		141.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.11		4.00		4.00	
Ca++	2.1-2.6 (MMOL/L)	01/06/91	2.31				2.29	
PO4--	0.6-1.4 (MMOL/L)	01/06/91	0.98				1.22	
SGOT	11-55 (U/L)	01/06/91	57.00	>	29.00		24.00	
GAMMA GT	5-60 (U/L)	01/06/91			188.00	>>		
ALK. PHOSPH.	35-110 (U/L)	01/06/91	198.00	>	118.00	>	122.00 >	
GLUCOSE	3.3-6.4 (MMOL/L)	01/06/91	4.50		5.20		5.00	
UREA	2.5-7.7 (MMOL/L)	01/06/91	4.20		3.60		4.10	
CREATININE	0.03-0.11 (MMOL/L)	01/06/91	0.06		0.06		0.04	
URIC ACID	0.12-0.42 (MMOL/L)	01/06/91					0.27	
TOT BILIRUBIN	3-18 (UMOL/L)	01/06/91	14.00		6.00		1.00 <	
TOT. PROTEINS	61-84 (G/L)	01/06/91	75.00		70.00		67.00	
ALBUMINE	35-50 (G/L)	01/06/91	39.00		41.00		42.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	01/06/91			5.60	>	6.00 >	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/06/91			2.40	>	3.80 >>	
GLOBULINS ALPHA 1	2-6 (G/L)	01/06/91	4.00		2.00			
GLOBULINS ALPHA 2	4-9 (G/L)	01/06/91	11.00	>	6.00			
GLOBULINS BETA	6-11 (G/L)	01/06/91	9.00		7.00			
GLOBULINS GAMMA	8-18 (G/L)	01/06/91	14.00		9.00			
TSH	0.15-3.5 (MU/L)	01/06/91	1.00					
T4	9.4-25 (NMOL/L)	01/06/91	29.50	>>				

1943

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 13 Patient: 16 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 42	
			03/12/91		06/01/92		20/01/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	03/04/91	15.80		16.40		16.50	
HT	40-54 (%)	03/04/91	45.30		46.30		47.00	
RBC	4.5-6.5 (10 ¹² /L)	03/04/91	4.96		5.10		5.16	
WBC	4-11 (10 ⁹ /L)	03/04/91	6.20		6.40		8.40	
WBC: N	2-8 (10 ⁹ /L)	03/04/91	4.20		4.50		6.10	
WBC: L	1-4 (10 ⁹ /L)	03/04/91	1.50		1.20		1.70	
WBC: E	0-0.6 (10 ⁹ /L)	03/04/91	0.10		0.10		0.20	
WBC: M	0-1 (10 ⁹ /L)	03/04/91	0.30		0.50		0.30	
WBC: B	0-0.2 (10 ⁹ /L)	03/04/91	0.10		0.10		0.10	
PLATELETS	150-450 (10 ⁹ /L)	03/04/91	220.00		207.00		239.00	
NA+	136-146 (MMOL/L)	03/04/91	146.00		141.00		145.00	
K+	3.5-5 (MMOL/L)	03/04/91	3.80		4.20		3.80	
CL-	95-110 (MMOL/L)	03/04/91	101.00		97.00		100.00	
Ca++	2.15-2.65 (MMOL/L)	03/04/91	2.32		2.31		2.39	
PO4--	0.8-1.4 (MMOL/L)	03/04/91	1.00		1.00		1.00	
SGOT	0-40 (U/L)	03/04/91	33.00		33.00		42.00	>
SGPT	0-40 (U/L)	03/04/91	26.00		31.00		34.00	>
LDH	250-520 (U/L)	03/04/91			313.00			
ALK. PHOSPH.	30-120 (U/L)	03/04/91	86.00		86.00		87.00	
GLUCOSE	4-5.5 (MMOL/L)	03/04/91	4.90		5.10		4.90	
UREA	2.3-7.6 (MMOL/L)	03/04/91	8.20	>	8.30	>	8.30	>
CREATININE	0.05-0.11 (MMOL/L)	03/04/91	0.10		0.10		0.09	
URIC ACID	0.18-0.48 (MMOL/L)	03/04/91	0.43		0.42		0.41	
TOT BILIRUBIN	0-20 (UMOL/L)	03/04/91	12.00		14.00		15.00	
TOT. PROTEINS	60-80 (G/L)	03/04/91	76.00		76.00		83.00	>
ALBUMINE	35-50 (G/L)	03/04/91	46.00		46.00		54.00	>
TOT. CHOLEST.	3-5.5 (MMOL/L)	03/04/91	4.50		4.60		5.50	
TRIGLYCERIDES	0.5-2 (MMOL/L)	03/04/91	1.30		1.00		1.40	
TSH	0.5-4 (MIU/L)	03/04/91	1.80					
T4	10-19 (PMOL/L)	03/04/91	18.20					

19/4

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 13 Patient: 17 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			23/05/92		11/06/92		02/07/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	03/04/91	13.60		14.50		13.90	
HT	40-54 (%)	03/04/91	39.30 <		40.40		39.30 <	
RBC	4.5-6.5 (10 ⁹ /L)	03/04/91	4.25 <		4.49 <		4.34 <	
WBC	4-11 (10 ⁹ /L)	03/04/91	4.70		5.40		5.30	
WBC: N	2-8 (10 ⁹ /L)	03/04/91	2.40		3.00		2.80	
WBC: L	1-4 (10 ⁹ /L)	03/04/91	1.70		1.80		1.90	
WBC: E	0-0.6 (10 ⁹ /L)	03/04/91	0.20		0.20		0.20	
WBC: M	0-1 (10 ⁹ /L)	03/04/91	0.40		0.40		0.50	
WBC: B	0-0.2 (10 ⁹ /L)	03/04/91	0.00		0.00		0.00	
PLATELETS	150-450 (10 ⁹ /L)	03/04/91	181.00		209.00		197.00	
NA+	136-146 (MMOL/L)	03/04/91	140.00		138.00		140.00	
K+	3.5-5 (MMOL/L)	03/04/91	4.20		4.60		4.40	
CL-	95-110 (MMOL/L)	03/04/91	100.00		101.00		101.00	
Ca++	2.15-2.65 (MMOL/L)	03/04/91	2.22		2.39		2.37	
PO4--	0.8-1.4 (MMOL/L)	03/04/91	1.00		1.10		1.10	
SGOT	0-40 (U/L)	03/04/91	17.00		35.00		19.00	
GAMMA GT	0-45 (U/L)	03/04/91	17.00		15.00		16.00	
LDH	250-520 (U/L)	03/04/91	220.00 <					
ALK. PHOSPH.	30-120 (U/L)	03/04/91	57.00		59.00		61.00	
GLUCOSE	4-5.5 (MMOL/L)	03/04/91	4.80		4.30		4.80	
UREA	2.3-7.6 (MMOL/L)	03/04/91	5.80		6.20		5.90	
CREATININE	0.05-0.11 (MMOL/L)	03/04/91	0.08		0.09		0.09	
URIC ACID	0.18-0.48 (MMOL/L)	03/04/91	0.32		0.33		0.32	
TOT BILIRUBIN	0-20 (UMOL/L)	03/04/91	10.00		19.00		13.00	
TOT. PROTEINS	60-80 (G/L)	03/04/91	69.00		74.00		74.00	
ALBUMINE	35-50 (G/L)	03/04/91	40.00		46.00		47.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	03/04/91	5.30		5.10		4.70	
TRIGLYCERIDES	0.5-2 (MMOL/L)	03/04/91	0.40 <		0.80		0.70	
TSH	0.5-4 (MIU/L)	03/04/91	1.30					
T4	10-19 (PMOL/L)	03/04/91	17.80					

1945

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 13 Patient: 18 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/06/92		13/07/92		03/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	03/04/91	15.00		14.80		15.20	
HT	40-54 (X)	03/04/91	43.30		44.60		44.60	
RBC	4.5-6.5 (10 ¹² /L)	03/04/91	4.97		5.03		5.07	
WBC	4-11 (10 ⁹ /L)	03/04/91	5.50		6.00		7.70	
WBC: N	2-8 (10 ⁹ /L)	03/04/91	3.20		3.40		4.60	
WBC: L	1-4 (10 ⁹ /L)	03/04/91	1.90		2.20		2.40	
WBC: E	0-0.6 (10 ⁹ /L)	03/04/91	0.20		0.20		0.30	
WBC: M	0-1 (10 ⁹ /L)	03/04/91	0.20		0.20		0.30	
WBC: B	0-0.2 (10 ⁹ /L)	03/04/91	0.10		0.10		0.10	
PLATELETS	150-450 (10 ⁹ /L)	03/04/91	173.00		175.00		177.00	
NA+	136-146 (MMOL/L)	03/04/91	142.00		141.00		141.00	
K+	3.5-5 (MMOL/L)	03/04/91	4.40		4.40		4.30	
CL-	95-110 (MMOL/L)	03/04/91	104.00		104.00		100.00	
Ca++	2.15-2.65 (MMOL/L)	03/04/91	2.31		2.32		2.35	
PO4--	0.8-1.4 (MMOL/L)	03/04/91	0.90		1.10		1.10	
SGPT	0-40 (U/L)	03/04/91	25.00		22.00		36.00	
GAMMA GT	0-45 (U/L)	03/04/91	28.00		25.00		25.00	
LDH	250-520 (U/L)	03/04/91					401.00	
ALK. PHOSPH.	30-120 (U/L)	03/04/91	55.00		55.00		58.00	
GLUCOSE	4-5.5 (MMOL/L)	03/04/91	5.50		5.90 >		5.10	
UREA	2.3-7.6 (MMOL/L)	03/04/91	7.30		7.10		4.10	
CREATININE	0.05-0.11 (MMOL/L)	03/04/91	0.08		0.09		0.09	
URIC ACID	0.18-0.48 (MMOL/L)	03/04/91			0.33		0.36	
TOT BILIRUBIN	0-20 (UMOL/L)	03/04/91	10.00		7.00		10.00	
TOT. PROTEINS	60-80 (G/L)	03/04/91	75.00		72.00		72.00	
ALBUMINE	35-50 (G/L)	03/04/91	44.00		44.00		44.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	03/04/91	6.90 >		6.10 >		6.30 >	
TRIGLYCERIDES	0.5-2 (MMOL/L)	03/04/91	1.10		1.50		1.90	
TSH	0.5-4 (MIU/L)	03/04/91	1.10					
T4	10-19 (PMOL/L)	03/04/91	16.40					

1946

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 13 Patient: 409 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/12/91		03/01/92		22/01/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	03/04/91	14.30		14.20		13.10	
HT	40-54 (%)	03/04/91	42.80		42.20		40.20	
RBC	4.5-6.5 (10 ¹² /L)	03/04/91	4.46 <		4.45 <		4.26 <	
HBC	4-11 (10 ⁹ /L)	03/04/91	4.40		4.70		4.30	
HBC: N	2-8 (10 ⁹ /L)	03/04/91	2.70		2.60		2.50	
HBC: L	1-4 (10 ⁹ /L)	03/04/91	1.40		1.60		1.40	
HBC: E	0-0.6 (10 ⁹ /L)	03/04/91	0.00		0.10		0.10	
HBC: H	0-1 (10 ⁹ /L)	03/04/91	0.20		0.30		0.20	
HBC: B	0-0.2 (10 ⁹ /L)	03/04/91	0.00		0.00		0.00	
PLATELETS	150-450 (10 ⁹ /L)	03/04/91	243.00		215.00		208.00	
NA+	136-146 (MMOL/L)	03/04/91	138.00		140.00		142.00	
K+	3.5-5 (MMOL/L)	03/04/91	4.30		3.50		3.50	
CL-	95-110 (MMOL/L)	03/04/91	100.00		101.00		103.00	
Ca++	2.15-2.65 (MMOL/L)	03/04/91	2.16		2.17		2.15	
PO4--	0.8-1.4 (MMOL/L)	03/04/91	1.10		0.80		0.90	
SGOT	0-40 (U/L)	03/04/91	25.00		23.00		27.00	
SGPT	0-40 (U/L)	03/04/91	18.00		17.00		16.00	
LDH	250-520 (U/L)	03/04/91					477.00	
ALK. PHOSPH.	30-120 (U/L)	03/04/91	60.00		60.00		55.00	
GLUCOSE	4-5.5 (MMOL/L)	03/04/91	3.80 <		4.40		4.20	
UREA	2.3-7.6 (MMOL/L)	03/04/91	3.40		3.80		6.20	
CREATININE	0.05-0.11 (MMOL/L)	03/04/91	0.08		0.09		0.08	
URIC ACID	0.18-0.48 (MMOL/L)	03/04/91	0.30		0.33		0.37	
TOT. BILIRUBIN	0-20 (UMOL/L)	03/04/91	9.00		15.00		13.00	
TOT. PROTEINS	60-80 (G/L)	03/04/91	72.00		67.00		70.00	
ALBUMINE	35-50 (G/L)	03/04/91	41.00		40.00		41.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	03/04/91			6.40 >		5.50	
TRIGLYCERIDES	0.5-2 (MMOL/L)	03/04/91			1.00		1.20	
TSH	0.5-4 (MIU/L)	03/04/91	2.10					
T4	10-19 (PMOL/L)	03/04/91	17.40					

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(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 13 Patient: 410 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/02/92		06/03/92		27/03/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	03/04/91	14.40		14.50		13.60	
HT	40-54 (%)	03/04/91	42.20		43.60		40.30	
RBC	4.5-6.5 (10 ¹² /L)	03/04/91	4.71		4.90		4.56	
WBC	4-11 (10 ⁹ /L)	03/04/91	8.50		7.30		6.40	
WBC: N	2-8 (10 ⁹ /L)	03/04/91	5.60		5.20		3.90	
WBC: L	1-4 (10 ⁹ /L)	03/04/91	2.90		1.70		1.90	
WBC: E	0-0.6 (10 ⁹ /L)	03/04/91	0.00		0.10		0.10	
WBC: M	0-1 (10 ⁹ /L)	03/04/91	0.00		0.30		0.40	
WBC: B	0-0.2 (10 ⁹ /L)	03/04/91	0.00		0.10		0.00	
PLATELETS	150-450 (10 ⁹ /L)	03/04/91	316.00		295.00		260.00	
NA+	136-146 (MMOL/L)	03/04/91	140.00		142.00			
K+	3.5-5 (MMOL/L)	03/04/91	3.80		3.70			
CL-	95-110 (MMOL/L)	03/04/91	108.00		104.00			
Ca++	2.15-2.65 (MMOL/L)	03/04/91	2.18		2.15		2.18	
PO4--	0.8-1.4 (MMOL/L)	03/04/91	0.90		1.00		1.10	
SGOT	0-40 (U/L)	03/04/91	28.00		31.00		30.00	
GAMMA GT	0-45 (U/L)	03/04/91	19.00		18.00		17.00	
LDH	250-520 (U/L)	03/04/91	309.00		273.00		243.00 <	
ALK. PHOSPH.	30-120 (U/L)	03/04/91	77.00		70.00		62.00	
GLUCOSE	4-5.5 (MMOL/L)	03/04/91	4.40		3.90 <		3.90 <	
UREA	2.3-7.6 (MMOL/L)	03/04/91	4.80		6.10			
CREATININE	0.05-0.11 (MMOL/L)	03/04/91	0.09		0.10			
URIC ACID	0.18-0.48 (MMOL/L)	03/04/91	0.25		0.28		0.26	
TOT. BILIRUBIN	0-20 (UMOL/L)	03/04/91	13.00		16.00		12.00	
TOT. PROTEINS	60-80 (G/L)	03/04/91	66.00		71.00		66.00	
ALBUMINE	35-50 (G/L)	03/04/91	38.00		40.00		40.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	03/04/91	4.20		4.30		4.50	
TRIGLYCERIDES	0.5-2 (MMOL/L)	03/04/91	0.90		0.80		0.90	
TSH	0.5-4 (MIU/L)	03/04/91	0.90					
T4	10-19 (PMOL/L)	03/04/91	18.30					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 13 Patient: 411 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/03/92		16/04/92		05/05/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/03/92	12.30	<	13.40		12.30 <	
HT	42-54 (%)	01/03/92	38.00	<	41.60	<	38.30 <	
RBC	4-6 (10 ¹² /L)	01/03/92	4.15		4.58		4.19	
WBC	4-11 (10 ⁹ /L)	01/03/92	9.56		5.98		5.71	
WBC: N	2.27-7.68 (10 ⁹ /L)	01/03/92	3.82		3.56		2.91	
WBC: L	0.83-3.14 (10 ⁹ /L)	01/03/92	4.87	>>	1.86		2.18	
WBC: E	0-0.49 (10 ⁹ /L)	01/03/92	0.57	>	0.24		0.40	
WBC: M	0.12-0.8 (10 ⁹ /L)	01/03/92	0.19		0.28		0.16	
WBC: B	0-0.16 (10 ⁹ /L)	01/03/92	0.00		0.04		0.06	
PLATELETS	150-350 (10 ⁹ /L)	01/03/92	241.00		405.00	>	293.00	
NA+	135-145 (MMOL/L)	01/03/92	142.00		139.00		141.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.40		3.80		4.10	
CL-	95-105 (MMOL/L)	01/03/92			102.00			
Ca++	2.1-2.6 (MMOL/L)	01/03/92	2.30		2.36		2.37	
PO4--	0.6-1.4 (MMOL/L)	01/03/92	1.20		1.20		1.29	
SGOT	11-55 (U/L)	01/03/92			35.00			
SGPT	30-65 (U/L)	01/03/92					23.00 <	
LDH	120-240 (U/L)	01/03/92			133.00			
ALK. PHOSPH.	35-110 (U/L)	01/03/92	35.00		43.00		41.00	
GLUCOSE	3.3-6.4 (MMOL/L)	01/03/92	4.90		5.30		5.50	
UREA	2.5-7.7 (MMOL/L)	01/03/92	4.90		4.10		2.90	
CREATININE	0.03-0.11 (MMOL/L)	01/03/92	0.09		0.08		0.08	
URIC ACID	0.12-0.42 (MMOL/L)	01/03/92			0.08		0.18	
TOT BILIRUBIN	3-18 (UMOL/L)	01/03/92	8.00				4.00	
TOT. PROTEINS	61-84 (G/L)	01/03/92	63.00		74.00		65.00	
ALBUMINE	35-50 (G/L)	01/03/92	38.00		44.00		40.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	01/03/92					4.60	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/03/92					1.10	
GLOBULINS ALPHA 1	2-6 (G/L)	01/03/92					3.00	
GLOBULINS ALPHA 2	4-9 (G/L)	01/03/92					5.00	
GLOBULINS BETA	6-11 (G/L)	01/03/92					7.00	
GLOBULINS GAMMA	8-18 (G/L)	01/03/92					11.00	
TSH	0.15-3.5 (MU/L)	01/03/92	1.60					
T4	9.4-25 (NMOL/L)	01/03/92	13.20					

1949

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 13 Patient: 423 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/09/92		05/10/92		29/10/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	03/04/91	13.80		14.20		12.80 <	
HT	40-54 (X)	03/04/91	40.10		40.70		37.70 <	
RBC	4.5-6.5 (10 ¹² /L)	03/04/91	4.06 <		4.17 <		3.93 <	
HBC	4-11 (10 ⁹ /L)	03/04/91	8.20		6.60		5.80	
HBC: N	2-8 (10 ⁹ /L)	03/04/91	5.20		4.00		3.50	
HBC: L	1-4 (10 ⁹ /L)	03/04/91	2.10		1.90		1.60	
HBC: E	0-0.6 (10 ⁹ /L)	03/04/91	0.30		0.20		0.20	
HBC: M	0-1 (10 ⁹ /L)	03/04/91	0.60		0.40		0.50	
HBC: B	0-0.2 (10 ⁹ /L)	03/04/91	0.00		0.10		0.10	
PLATELETS	150-450 (10 ⁹ /L)	03/04/91	236.00		298.00		242.00	
NA+	136-146 (MMOL/L)	03/04/91	134.00 <		137.00			
K+	3.5-5 (MMOL/L)	03/04/91	4.50		4.20			
CL-	95-110 (MMOL/L)	03/04/91	97.00		99.00			
Ca++	2.15-2.65 (MMOL/L)	03/04/91	2.14 <		2.22		2.18	
PO4--	0.8-1.4 (MMOL/L)	03/04/91	1.10		1.20		1.00	
SGPT	0-40 (U/L)	03/04/91	49.00 >		46.00 >			
GAMMA GT	0-45 (U/L)	03/04/91	15.00		17.00			
LDH	250-520 (U/L)	03/04/91	450.00				434.00	
ALK. PHOSPH.	30-120 (U/L)	03/04/91	73.00		77.00			
GLUCOSE	4-5.5 (MMOL/L)	03/04/91	4.40		4.70		4.50	
UREA	2.3-7.6 (MMOL/L)	03/04/91	2.60		2.20 <			
CREATININE	0.05-0.11 (MMOL/L)	03/04/91	0.08		0.08			
URIC ACID	0.18-0.48 (MMOL/L)	03/04/91	0.35		0.31		0.29	
TOT BILIRUBIN	0-20 (UMOL/L)	03/04/91	11.00		12.00			
TOT. PROTEINS	60-80 (G/L)	03/04/91	74.00		76.00		63.00	
ALBUMINE	35-50 (G/L)	03/04/91	43.00		42.00		38.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	03/04/91	4.30		4.70		4.50	
TRIGLYCERIDES	0.5-2 (MMOL/L)	03/04/91	2.40 >		2.70 >>		1.40	
TSH	0.5-4 (MIU/L)	03/04/91	0.50					
T4	10-19 (PMOL/L)	03/04/91	15.80					

1950

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 14 Patient: 19 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 28	
			03/04/92		01/05/92		07/05/92	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	115-160 (G/L)	10/03/92	156.00		154.00		149.00	
HT	0.37-0.47 (L/L)	10/03/92	0.46		0.44		0.44	
RBC	3.8-5.8 (10 ⁶ /UL)	10/03/92	5.47		5.31		5.03	
WBC	4-11 (10 ³ /UL)	10/03/92	6.90		9.40		11.80 >	
WBC: N	2.5-7.5 (10 ³ /UL)	10/03/92	5.22		6.70		9.78 >>	
WBC: L	1.5-4 (10 ³ /UL)	10/03/92	0.92 <<		1.68		1.09 <	
WBC: E	0.04-0.44 (10 ³ /UL)	10/03/92	0.06		0.16		0.04	
WBC: M	0.2-0.8 (10 ³ /UL)	10/03/92	0.65		0.83 >		0.80	
WBC: B	0.01-0.1 (10 ³ /UL)	10/03/92	0.08		0.04		0.05	
PLATELETS	150-400 (10 ³ /UL)	10/03/92	311.00		402.00 >		414.00 >	
NA+	135-145 (MMOL/L)	10/03/92	142.00		142.00		139.00	
K+	3.5-5 (MMOL/L)	10/03/92	4.30		3.70		4.40	
CL-	92-107 (MMOL/L)	10/03/92	106.00		103.00		104.00	
Ca++	2.13-2.62 (MMOL/L)	10/03/92	2.44		2.40		2.59	
PO4--	0.73-1.37 (MMOL/L)	10/03/92	1.17		1.06		1.04	
SGOT	5-43 (IU/L)	10/03/92	14.00		21.00		6.00	
SGPT	5-55 (IU/L)	10/03/92	15.00		13.00		19.00	
GAMMA GT	5-50 (IU/L)	10/03/92	13.00		17.00		25.00	
LDH	210-420 (IU/L)	10/03/92	300.00				433.00 >	
ALK. PHOSPH.	50-90 (IU/L)	10/03/92	127.00 >		121.00 >		120.00 >	
GLUCOSE	3.6-5.3 (MMOL/L)	10/03/92	7.40 >>		4.20		6.80 >	
UREA	2.5-8.3 (MMOL/L)	10/03/92	5.60		4.20		4.90	
CREATININE	0.05-0.11 (MMOL/L)	10/03/92	0.08		0.08		0.08	
URIC ACID	0.18-0.42 (MMOL/L)	10/03/92	0.27		0.28		0.31	
TOT BILIRUBIN	3-19 (UMOL/L)	10/03/92	9.00		5.00		6.00	
TOT. PROTEINS	61-83 (G/L)	10/03/92	72.00		78.00		76.00	
ALBUMINE	35-50 (G/L)	10/03/92	40.00		40.00		41.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	10/03/92	6.00 >		5.60 >		6.00 >	
TRIGLYCERIDES	0.17-2 (MMOL/L)	10/03/92	1.73		1.77		1.50	
TSH	0.1-4 (MU/L)	10/03/92	0.93					
T4	9-27 (PMOL/L)	10/03/92	13.00					

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(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done (*) missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 14 Patient: 20 Treatment: Imipramine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			27/04/92		20/05/92		19/06/92	
			value	(±)	value	(±)	value	(±)
Laboratory test	Range value	Range date						
HB	115-160 (G/L)	10/03/92	152.00		141.00		137.00	
HT	0.37-0.47 (L/L)	10/03/92	0.46		0.44		0.42	
RBC	3.8-5.8 (10 ⁶ /UL)	10/03/92	5.07		4.73		4.61	
HBC	4-11 (10 ³ /UL)	10/03/92	6.10		4.20		3.40 <	
HBC: N	2.5-7.5 (10 ³ /UL)	10/03/92	4.45		2.89		2.24 <	
HBC: L	1.5-4 (10 ³ /UL)	10/03/92	1.32 <		1.02 <<		0.81 <<	
HBC: E	0.04-0.44 (10 ³ /UL)	10/03/92			0.11		0.06	
HBC: M	0.2-0.8 (10 ³ /UL)	10/03/92	0.23		0.14 <		0.20	
HBC: B	0.01-0.1 (10 ³ /UL)	10/03/92			0.01		0.03	
PLATELETS	150-400 (10 ³ /UL)	10/03/92	300.00		293.00		243.00	
NA+	135-145 (MMOL/L)	10/03/92	138.00		137.00		142.00	
K+	3.5-5 (MMOL/L)	10/03/92	3.90		4.00		4.70	
CL-	92-107 (MMOL/L)	10/03/92	107.00		103.00		105.00	
Ca++	2.13-2.62 (MMOL/L)	10/03/92	2.39		2.25		2.25	
PO4--	0.73-1.37 (MMOL/L)	10/03/92	1.17		1.28		1.25	
SGOT	5-43 (IU/L)	10/03/92	22.00		16.00		32.00	
SGPT	5-55 (IU/L)	10/03/92	18.00		20.00		53.00	
GAMMA GT	5-50 (IU/L)	10/03/92	21.00		31.00		38.00	
LDH	210-420 (IU/L)	10/03/92	396.00		335.00		423.00 >	
ALK. PHOSPH.	50-90 (IU/L)	10/03/92	83.00		78.00		74.00	
GLUCOSE	3.6-5.3 (MMOL/L)	10/03/92	6.50 >		5.30		5.90 >	
UREA	2.5-8.3 (MMOL/L)	10/03/92	4.00		5.40		6.20	
CREATININE	0.05-0.11 (MMOL/L)	10/03/92	0.10		0.08		0.08	
URIC ACID	0.18-0.42 (MMOL/L)	10/03/92	0.22		0.22		0.24	
TOT. BILIRUBIN	3-19 (UMOL/L)	10/03/92	7.00		7.00		8.00	
TOT. PROTEINS	61-83 (G/L)	10/03/92	76.00		71.00		74.00	
ALBUMINE	35-50 (G/L)	10/03/92	40.00		36.00		37.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	10/03/92	4.80		5.20		5.50	
TRIGLYCERIDES	0.17-2 (MMOL/L)	10/03/92	1.39		1.51		1.02	
TSH	0.1-4 (MU/L)	10/03/92	1.70					
T4	9-27 (PMOL/L)	10/03/92	13.00					

1952

(±) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 14 Patient: 21 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 35	
			16/07/92		10/08/92		24/08/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	115-160 (G/L)	10/03/92	145.00		128.00		132.00	
HT	0.37-0.47 (L/L)	10/03/92	0.45		0.44		0.44	
RBC	3.8-5.8 (10 ⁶ /UL)	10/03/92	5.12		4.43		4.68	
WBC	4-11 (10 ³ /UL)	10/03/92	5.30		4.50		6.20	
WBC: N	2.5-7.5 (10 ³ /UL)	10/03/92	3.69		2.87		4.41	
WBC: L	1.5-4 (10 ³ /UL)	10/03/92	1.38 <		1.34 <		1.59	
WBC: E	0.04-0.44 (10 ³ /UL)	10/03/92	0.04		0.05		0.09	
WBC: M	0.2-0.8 (10 ³ /UL)	10/03/92	0.13 <		0.22		0.13 <	
WBC: B	0.01-0.1 (10 ³ /UL)	10/03/92	0.04		0.05		0.04	
PLATELETS	150-400 (10 ³ /UL)	10/03/92	268.00		292.00		345.00	
NA+	135-145 (MMOL/L)	10/03/92	140.00		138.00		139.00	
K+	3.5-5 (MMOL/L)	10/03/92	4.00		4.20		4.10	
CL-	92-107 (MMOL/L)	10/03/92			104.00		102.00	
Ca++	2.13-2.62 (MMOL/L)	10/03/92	2.39		2.23		2.23	
PO4--	0.73-1.37 (MMOL/L)	10/03/92	1.05		1.10		1.19	
SGOT	5-43 (IU/L)	10/03/92	24.00		17.00		18.00	
SGPT	5-55 (IU/L)	10/03/92	26.00		18.00		17.00	
GAMMA GT	5-50 (IU/L)	10/03/92	23.00		15.00		18.00	
LDH	210-420 (IU/L)	10/03/92	344.00		359.00		332.00	
ALK. PHOSPH.	50-90 (IU/L)	10/03/92	98.00 >		78.00		74.00	
GLUCOSE	3.6-5.3 (MMOL/L)	10/03/92	5.60 >		4.90		5.10	
UREA	2.5-8.3 (MMOL/L)	10/03/92	5.50		4.90		4.30	
CREATININE	0.05-0.11 (MMOL/L)	10/03/92	0.07		0.07		0.05	
URIC ACID	0.18-0.42 (MMOL/L)	10/03/92	0.20		0.17 <		0.22	
TOT BILIRUBIN	3-19 (UMOL/L)	10/03/92	10.00		7.00		6.00	
TOT. PROTEINS	61-83 (G/L)	10/03/92	82.00		75.00		77.00	
ALBUMINE	35-50 (G/L)	10/03/92	46.00		36.00		37.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	10/03/92	6.70 >		6.00 >		6.90 >	
TRIGLYCERIDES	0.17-2 (MMOL/L)	10/03/92	0.89		0.97		0.89	
TSH	0.1-4 (MU/L)	10/03/92	0.61					
T4	9-27 (PMOL/L)	10/03/92	19.00					

1952

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 15 Patient: 25 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/06/91		09/07/91		30/07/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	16.20		15.90		16.60 >	
HT	0.35-0.47 (L/L)	18/05/91	0.46		0.47		0.48 >	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	5.07		5.05		5.15	
HBC	3.5-12 (10 ⁹ /L)	18/05/91	9.80		8.50		9.40	
HBC: N	2.5-8 (10 ⁹ /L)	18/05/91	5.80		5.10		6.40	
HBC: L	1.2-4 (10 ⁹ /L)	18/05/91	3.40		2.80		2.80	
HBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
HBC: H	0.1-1.1 (10 ⁹ /L)	18/05/91	0.60		0.50		0.20	
HBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	396.00		365.00		421.00 >	
NA+	135-145 (MMOL/L)	18/05/91	139.00		136.00		140.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	5.00 >		4.60 >		4.90 >	
CL-	95-105 (MMOL/L)	18/05/91	102.00		99.00		99.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.50		2.39		2.39	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.50 >>		1.00		1.05	
SGOT	0-35 (U/L)	18/05/91	18.00		24.00		18.00	
GAMMA GT	5-23 (U/L)	18/05/91	45.00 >		40.00 >		45.00 >	
LDH	70-170 (U/L)	18/05/91	174.00 >		164.00		162.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	90.00 >		86.00 >		100.00 >	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	5.70		6.80 >		6.40	
UREA	2.5-7.5 (MMOL/L)	18/05/91	3.10		2.80		3.60	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.06		0.07		0.07	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.44 >		0.46 >		0.41 >	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	8.00		8.00		7.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	2.00		2.00		2.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	76.00		70.00		74.00	
ALBUMINE	36-49 (G/L)	18/05/91	50.00 >		46.00		48.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	7.80		6.40		6.40	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	5.10 >>		3.60 >>		4.20 >>	
TSH	0.5-6.5 (MIU/L)	18/05/91	1.39					
T4	86-148 (NMOL/L)	18/05/91	120.00					

1954

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 15 Patient: 26 Treatment: Placebo Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/06/91		10/07/91		01/08/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	13.5-17.5 (G/DL)	18/05/91	15.70		14.50		15.90	
HT	0.4-0.54 (L/L)	18/05/91	0.45		0.43		0.47	
RBC	4.5-6.5 (10 ¹² /L)	18/05/91	5.26		4.91		5.33	
WBC	3.5-10 (10 ⁹ /L)	18/05/91	8.20		7.40		7.10	
WBC: N	1.5-6.5 (10 ⁹ /L)	18/05/91	5.20		5.70		4.70	
WBC: L	1.2-4 (10 ⁹ /L)	18/05/91	2.70		1.20		1.40	
WBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00		0.10	
WBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.40		0.50		0.60	
WBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.30 >>	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	300.00		295.00		273.00	
NA+	135-145 (MMOL/L)	18/05/91	140.00		134.00 <		142.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.40		4.40		4.30	
CL-	95-105 (MMOL/L)	18/05/91	103.00		98.00		104.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.39		2.18 <		2.30	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.44 >		1.02		1.13	
SGOT	0-35 (U/L)	18/05/91	34.00		36.00 >		30.00	
GAMMA GT	5-23 (U/L)	18/05/91	58.00 >>		48.00 >>		44.00 >	
LDH	70-170 (U/L)	18/05/91	179.00 >		212.00 >		164.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	74.00 >		96.00 >		86.00 >	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	5.30		5.40		5.80	
UREA	2.5-7.5 (MMOL/L)	18/05/91	6.50		5.20		7.90 >	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.08		0.08		0.09	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.37		0.38		0.40 >	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	15.00		17.00		13.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	3.00		3.00		3.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	76.00		71.00		76.00	
ALBUMINE	36-49 (G/L)	18/05/91	49.00		43.00		47.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	5.50		3.60		5.00	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	5.30 >>		1.40		2.30 >>	
TSH	0.5-6.5 (MIU/L)	18/05/91	2.68					
T4	86-148 (NMOL/L)	18/05/91	108.00					

1955

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 15 Patient: 27 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/06/91		23/07/91		13/08/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	11.80		10.70 <	12.00		
HT	0.35-0.47 (L/L)	18/05/91	0.35		0.34 <	0.36		
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	3.81 <		3.78 <	3.92		
WBC	3.5-12 (10 ⁹ /L)	18/05/91	6.70		7.30	7.20		
WBC: N	2.5-8 (10 ⁹ /L)	18/05/91	3.80		4.60	4.40		
WBC: L	1.2-4 (10 ⁹ /L)	18/05/91	2.50		2.30	2.40		
WBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00	0.00		
WBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.40		0.40	0.40		
WBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00	0.00		
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	329.00		338.00	330.00		
NA+	135-145 (MMOL/L)	18/05/91	137.00		138.00	136.00		
K+	3.5-4.5 (MMOL/L)	18/05/91	4.00		4.20	4.30		
CL-	95-105 (MMOL/L)	18/05/91	101.00		100.00	96.00		
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.32		2.21 <	2.23 <		
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.08		0.96	1.07		
SGOT	0-35 (U/L)	18/05/91	20.00		17.00	18.00		
GAMMA GT	5-23 (U/L)	18/05/91	18.00		18.00	17.00		
LDH	70-170 (U/L)	18/05/91				188.00 >		
ALK. PHOSPH.	18-70 (U/L)	18/05/91	33.00		26.00	32.00		
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	5.00		4.50	5.10		
UREA	2.5-7.5 (MMOL/L)	18/05/91	7.00		8.90 >	9.50 >		
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.05		0.06	0.06		
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.19		0.19	0.20		
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	7.00		4.00	6.00		
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	1.00		2.00	1.00		
TOT. PROTEINS	68-83 (G/L)	18/05/91	62.00 <		59.00 <	63.00 <		
ALBUMINE	36-49 (G/L)	18/05/91	41.00		38.00	39.00		
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	4.80		4.90	5.40		
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	1.30		1.20	1.20		
TSH	0.5-6.5 (MIU/L)	18/05/91	1.25					
T4	86-148 (NMOL/L)	18/05/91	102.00					

1956

(φ) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 15 Patient: 28 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/08/91		29/08/91		20/09/91	
			value	(e)	value	(e)	value	(e)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	13.00		13.20		13.30	
HT	0.35-0.47 (L/L)	18/05/91	0.39		0.39		0.39	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	4.49		4.47		4.56	
HBC	3.5-12 (10 ⁹ /L)	18/05/91	10.00		6.30		7.20	
HBC: N	2.5-8 (10 ⁹ /L)	18/05/91	6.20		3.70		4.60	
HBC: L	1.2-4 (10 ⁹ /L)	18/05/91	3.40		2.10		2.20	
HBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
HBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.40		0.50		0.40	
HBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	353.00		297.00		311.00	
NA+	135-145 (MMOL/L)	18/05/91	138.00		136.00		138.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.00		4.10		3.80	
CL-	95-105 (MMOL/L)	18/05/91	104.00		103.00		104.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.28		2.40		2.32	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.11		1.02		0.85	
SGOT	0-35 (U/L)	18/05/91	20.00		17.00		19.00	
GAMMA GT	5-23 (U/L)	18/05/91	20.00		17.00		17.00	
LDH	70-170 (U/L)	18/05/91	154.00		149.00		154.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	61.00		52.00		61.00	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	4.30		3.40		3.40	
UREA	2.5-7.5 (MMOL/L)	18/05/91	4.10		5.60		3.60	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.07		0.08		0.08	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.31		0.29		0.29	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	8.00		9.00		11.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	2.00		2.00		3.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	71.00		70.00		69.00	
ALBUMINE	36-49 (G/L)	18/05/91	47.00		47.00		46.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	5.10		5.10		4.90	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	0.80		0.70		0.90	
TSH	0.5-6.5 (MIU/L)	18/05/91	1.51					
T4	86-148 (NMOL/L)	18/05/91	103.00					

1957

(e) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 15 Patient: 29 Treatment: Placebo Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			29/08/91		19/09/91	
			value (⊕)	value (⊕)	value (⊕)	value (⊕)
Laboratory test	Range value	Range date				
HB	13.5-17.5 (G/DL)	18/05/91	16.10		15.40	
HT	0.4-0.54 (L/L)	18/05/91	0.48		0.46	
RBC	4.5-6.5 (10 ¹² /L)	18/05/91	5.17		5.01	
WBC	3.5-10 (10 ⁹ /L)	18/05/91	8.30		10.00	
WBC: N	1.5-6.5 (10 ⁹ /L)	18/05/91	5.70		7.00	>
WBC: L	1.2-4 (10 ⁹ /L)	18/05/91	2.20		2.50	
WBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00	
WBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.30		0.50	
WBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	333.00		289.00	
NA+	135-145 (MMOL/L)	18/05/91	140.00		140.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.40		3.90	
CL-	95-105 (MMOL/L)	18/05/91	103.00		103.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.50		2.45	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.07		0.97	
SGOT	0-35 (U/L)	18/05/91	17.00		16.00	
GAMMA GT	5-23 (U/L)	18/05/91	28.00	>	30.00	>
LDH	70-170 (U/L)	18/05/91	160.00		163.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	73.00	>	70.00	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	5.00		6.50	
UREA	2.5-7.5 (MMOL/L)	18/05/91	4.80		6.40	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.10		0.09	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.30		0.28	
TOT. BILIRUBIN	0-17 (UMOL/L)	18/05/91	27.00	>	25.00	>
DIR. BILIRUBIN	0-5 (UMOL/L)	18/05/91	4.00		4.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	75.00		71.00	
ALBUMINE	36-49 (G/L)	18/05/91	50.00	>	48.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	5.70		5.70	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	1.20		1.40	
TSH	0.5-6.5 (MIU/L)	18/05/91	0.42	<<		
T4	86-148 (NMOL/L)	18/05/91	102.00			

1958

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 15 Patient: 30 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/09/91		24/09/91		15/10/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	14.20		13.80		15.40	
HT	0.35-0.47 (L/L)	18/05/91	0.41		0.40		0.44	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	4.42		4.35		4.85	
WBC	3.5-12 (10 ⁹ /L)	18/05/91	5.50		4.80		4.80	
WBC: N	2.5-8 (10 ⁹ /L)	18/05/91	3.40		3.10		2.90	
WBC: L	1.2-4 (10 ⁹ /L)	18/05/91	1.90		1.50		1.50	
WBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
WBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.20		0.20		0.40	
WBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	332.00		294.00		310.00	
NA+	135-145 (MMOL/L)	18/05/91	136.00		136.00		136.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	3.80		4.50		3.60	
CL-	95-105 (MMOL/L)	18/05/91	100.00		103.00		99.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.44		2.31		2.38	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.01		0.86		1.03	
SGOT	0-35 (U/L)	18/05/91	15.00		16.00		101.00 >>	
GAMMA GT	5-23 (U/L)	18/05/91	26.00 >		23.00		54.00 >>	
LDH	70-170 (U/L)	18/05/91	160.00		169.00		231.00 >	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	54.00		50.00		69.00	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	5.40		5.30		6.10	
UREA	2.5-7.5 (MMOL/L)	18/05/91	4.80		3.80		3.70	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.07		0.07		0.08	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.30		0.24		0.35	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	11.00		8.00		14.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	3.00		2.00		5.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	79.00		73.00		81.00	
ALBUMINE	36-49 (G/L)	18/05/91	50.00 >		45.00		49.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	5.10		4.50		5.60	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	1.50		0.80		1.10	
TSH	0.5-6.5 (MIU/L)	18/05/91	1.78					
T4	86-148 (NMOL/L)	18/05/91	92.00					

1959

(⊕) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 15 Patient: 403 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/10/91		28/10/91		14/11/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	13.60		13.40		13.80	
HT	0.35-0.47 (L/L)	18/05/91	0.39		0.39		0.40	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	4.47		4.43		4.57	
MBC	3.5-12 (10 ⁹ /L)	18/05/91	7.70		7.00		8.60	
MBC: N	2.5-8 (10 ⁹ /L)	18/05/91	5.80		5.70		7.10	
MBC: L	1.2-4 (10 ⁹ /L)	18/05/91	1.60		1.20		1.30	
MBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
MBC: H	0.1-1.1 (10 ⁹ /L)	18/05/91	0.30		0.20		0.20	
MBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	294.00		274.00		278.00	
NA+	135-145 (MMOL/L)	18/05/91	134.00	<	135.00		136.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.80	>	4.10		3.90	
CL-	95-105 (MMOL/L)	18/05/91	101.00		97.00		98.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.27		2.19	<	2.33	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.48	>	1.39	>	1.14	
SGOT	0-35 (U/L)	18/05/91	11.00		21.00		14.00	
GAMMA GT	5-23 (U/L)	18/05/91	20.00		21.00		20.00	
LDH	70-170 (U/L)	18/05/91	116.00		126.00		108.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	49.00		51.00		51.00	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	6.40		5.10		5.10	
UREA	2.5-7.5 (MMOL/L)	18/05/91	4.80		3.70		3.80	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.09		0.08		0.07	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.27		0.17		0.21	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	9.00		8.00		10.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	3.00		3.00		3.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	71.00		70.00		69.00	
ALBUMINE	36-49 (G/L)	18/05/91	48.00		47.00		46.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	4.30		3.90		4.20	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	1.30		1.70		1.00	
TSH	0.5-6.5 (MIU/L)	18/05/91	0.52					
T4	86-148 (NMOL/L)	18/05/91	111.00					

1960

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 15 Patient: 404 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			10/09/91	29/10/91
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	11.5-16.5 (G/DL)	18/05/91	13.70	14.40
HT	0.35-0.47 (L/L)	18/05/91	0.41	0.41
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	4.35	4.46
MBC	3.5-12 (10 ⁹ /L)	18/05/91	11.70	10.20
MBC: N	2.5-8 (10 ⁹ /L)	18/05/91	8.70	6.20
MBC: L	1.2-4 (10 ⁹ /L)	18/05/91	2.60	3.40
MBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00	0.00
MBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.50	0.60
MBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00	0.00
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	336.00	324.00
NA+	135-145 (MMOL/L)	18/05/91	138.00	133.00
K+	3.5-4.5 (MMOL/L)	18/05/91	3.90	3.80
CL-	95-105 (MMOL/L)	18/05/91	100.00	97.00
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.42	2.25
PO4--	0.6-1.3 (MMOL/L)	18/05/91	0.76	1.17
SGOT	0-35 (U/L)	18/05/91	20.00	29.00
GAMMA GT	5-23 (U/L)	18/05/91	29.00	67.00
LDH	70-170 (U/L)	18/05/91	162.00	155.00
ALK. PHOSPH.	18-70 (U/L)	18/05/91	56.00	62.00
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	4.40	5.30
UREA	2.5-7.5 (MMOL/L)	18/05/91	3.00	4.50
CREATININE	0.04-0.42 (MMOL/L)	18/05/91	0.08	0.10
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.38	0.40
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	11.00	9.00
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	4.00	2.00
TOT. PROTEINS	68-83 (G/L)	18/05/91	79.00	76.00
ALBUMINE	36-49 (G/L)	18/05/91	49.00	49.00
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	6.70	8.00
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	1.10	2.10
TSH	0.5-6.5 (MIU/L)	18/05/91	3.02	
T4	86-148 (NMOL/L)	18/05/91	112.00	

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1961

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 15 Patient: 405 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/11/91		02/12/91		23/12/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	13.20		13.70		13.00	
HT	0.35-0.47 (L/L)	18/05/91	0.38		0.40		0.38	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	4.20		4.36		4.20	
WBC	3.5-12 (10 ⁹ /L)	18/05/91	4.20		5.20		4.00	
WBC: N	2.5-8 (10 ⁹ /L)	18/05/91	1.80	<	2.80		2.10 <	
WBC: L	1.2-4 (10 ⁹ /L)	18/05/91	1.80		1.90		1.80	
WBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.20		0.00		0.00	
WBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.40		0.50		0.10	
WBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	246.00		235.00		233.00	
NA+	135-145 (MMOL/L)	18/05/91	142.00		141.00		142.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	3.80		4.10		4.20	
CL-	95-105 (MMOL/L)	18/05/91	104.00		101.00		104.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.37		2.24 <		2.21 <	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.27		1.38 >		1.30 <	
SGOT	0-35 (U/L)	18/05/91	18.00		17.00		15.00	
GAMMA GT	5-23 (U/L)	18/05/91	18.00		18.00		18.00	
LDH	70-170 (U/L)	18/05/91	139.00		132.00		129.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	52.00		53.00		52.00	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	4.50		4.90		4.20	
UREA	2.5-7.5 (MMOL/L)	18/05/91	4.50		4.30		4.60	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.05		0.05		0.05	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.21		0.19		0.24	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	15.00		14.00		15.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	3.00		3.00		3.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	68.00		66.00 <		67.00 <	
ALBUMINE	36-49 (G/L)	18/05/91	48.00		46.00		45.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	6.30		6.18		6.10	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	0.80		1.10		0.90	
TSH	0.5-6.5 (MIU/L)	18/05/91	2.58					
T4	86-148 (NMOL/L)	18/05/91	100.00					

1962

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
 < out of range (value lower than min range) > out of range (value higher than max range)
 ** missing laboratory test value nd laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 15 Patient: 406 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/11/91		17/12/91		07/01/92	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	13.5-17.5 (G/DL)	18/05/91	15.10		15.60		15.40	
HT	0.4-0.54 (L/L)	18/05/91	0.44		0.46		0.46	
RBC	4.5-6.5 (10 ¹² /L)	18/05/91	5.32		5.41		5.35	
HBC	3.5-10 (10 ⁹ /L)	18/05/91	9.40		7.60		7.90	
HBC: N	1.5-6.5 (10 ⁹ /L)	18/05/91	7.20	>	5.20		5.50	
HBC: L	1.2-4 (10 ⁹ /L)	18/05/91	1.60		1.50		1.80	
HBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.30		0.00	
HBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.60		0.60		0.60	
HBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	318.00		330.00		382.00	
NA+	135-145 (MMOL/L)	18/05/91	139.00		138.00		142.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.10		4.30		4.10	
CL-	95-105 (MMOL/L)	18/05/91	100.00		100.00		102.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.38		2.33		2.33	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.11		1.19		0.89	
SGOT	0-35 (U/L)	18/05/91	13.00		16.00		19.00	
GAMMA GT	5-23 (U/L)	18/05/91	23.00		29.00	>	32.00	
LDH	70-170 (U/L)	18/05/91	121.00		139.00		134.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	74.00	>	78.00	>	97.00	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	5.20		5.50		5.10	
UREA	2.5-7.5 (MMOL/L)	18/05/91	6.60		5.90		4.00	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.11		0.10		0.10	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.33		0.29		0.37	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	11.00		7.00		9.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	3.00		3.00		3.00	
TOT. PROTEINS	68-89 (G/L)	18/05/91	75.00		75.00		74.00	
ALBUMINE	36-49 (G/L)	18/05/91	49.00		49.00		47.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	6.20		6.80		6.80	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	2.60	>>	4.00	>>	2.00	
TSH	0.5-6.5 (MIU/L)	18/05/91	0.28	<<				
T4	86-148 (NMOL/L)	18/05/91	99.00					

1963

(ø) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 ** missing laboratory test value nd laboratory not done () missing range value

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Contro: 15 Patient: 407 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/12/91		24/12/91		14/01/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	15.20		15.00		14.70	
HT	0.35-0.47 (L/L)	18/05/91	0.45		0.44		0.42	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	5.05		4.90		4.82	
HBC	3.5-12 (10 ⁹ /L)	18/05/91	10.00		13.70 >		11.80	
WBC: N	2.5-8 (10 ⁹ /L)	18/05/91	6.40		9.40 >		8.00	
WBC: L	1.2-4 (10 ⁹ /L)	18/05/91	2.80		3.50		3.10	
WBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
WBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.70		0.80		0.80	
WBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	334.00		344.00		294.00	
NA+	135-145 (MMOL/L)	18/05/91	140.00		135.00		139.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.20		4.60 >		4.40	
CL-	95-105 (MMOL/L)	18/05/91	104.00		106.00 >		101.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.22 <		2.18 <		2.17 <	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.12		1.10		1.27	
SGOT	0-35 (U/L)	18/05/91	14.00		17.00		13.00	
GAMMA GT	5-23 (U/L)	18/05/91	19.00		20.00		19.00	
LDH	70-170 (U/L)	18/05/91	182.00 >		291.00 >		191.00 >	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	62.00		62.00		63.00	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	4.20		3.20 <		4.00	
UREA	2.5-7.5 (MMOL/L)	18/05/91	3.50		5.00		4.20	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.07		0.06		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.21		0.16		0.14	
TOT. BILIRUBIN	0-17 (UMOL/L)	18/05/91	11.00		8.00		8.00	
DIR. BILIRUBIN	0-5 (UMOL/L)	18/05/91	2.00				2.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	69.00		64.00 <		69.00	
ALBUMINE	36-49 (G/L)	18/05/91	46.00		42.00		46.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	4.20		4.00		4.00	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	1.30		1.10		1.70	
TSH	0.5-6.5 (MIU/L)	18/05/91	1.11					
T4	86-148 (NMOL/L)	18/05/91	100.00					

1964

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

LABORATORY DATA 9550082

Centre: 15 Patient: 408 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/01/92		10/02/92		04/03/92	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	13.20		13.00		14.00	
HT	0.35-0.47 (L/L)	18/05/91	0.39		0.39		0.41	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	4.24		4.13		4.43	
HBC	3.5-12 (10 ⁹ /L)	18/05/91	6.40		5.20		5.90	
HBC: N	2.5-8 (10 ⁹ /L)	18/05/91	4.50		3.30		3.50	
HBC: L	1.2-4 (10 ⁹ /L)	18/05/91	1.40		1.40		1.80	
HBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
HBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.50		0.50		0.60	
HBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	403.00 >		362.00		391.00	
NA+	135-145 (MMOL/L)	18/05/91	138.00		142.00		138.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.50		4.20		4.20	
CL-	95-105 (MMOL/L)	18/05/91	99.00		106.00 >		103.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.31		2.15 <		2.27	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.21		1.10		1.18	
SGOT	0-35 (U/L)	18/05/91	25.00		15.00		16.00	
GAMMA GT	5-23 (U/L)	18/05/91	48.00 >>		27.00 >		22.00	
LDH	70-170 (U/L)	18/05/91	165.00		153.00		147.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	88.00 >		77.00 >		77.00 >	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	4.90		4.10		5.10	
UREA	2.5-7.5 (MMOL/L)	18/05/91	5.50		6.40		5.40	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.08		0.07		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.15		0.07 <		0.11	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	4.00		5.00		7.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	1.00		2.00		2.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	63.00 <		67.00 <		69.00	
ALBUMINE	36-49 (G/L)	18/05/91	42.00		45.00		46.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	7.00		6.90		7.20	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	0.80		1.50		1.00	
TSH	0.5-6.5 (MIU/L)	18/05/91	0.82					
T4	86-148 (NMOL/L)	18/05/91	91.00					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 15 Patient: 418 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/01/92		20/02/92		12/03/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	14.10		13.20		13.00	
HT	0.35-0.47 (L/L)	18/05/91	0.41		0.39		0.39	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	4.79		4.55		4.48	
WBC	3.5-12 (10 ⁹ /L)	18/05/91	5.10		6.80		5.50	
WBC: N	2.5-8 (10 ⁹ /L)	18/05/91	3.10		4.70		3.50	
WBC: L	1.2-4 (10 ⁹ /L)	18/05/91	1.50		1.70		1.60	
WBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.10		0.00		0.00	
WBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.40		0.40		0.50	
WBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	365.00		379.00		375.00	
NA+	135-145 (MMOL/L)	18/05/91	140.00		140.00		134.00 <	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.20		3.60		3.80	
CL-	95-105 (MMOL/L)	18/05/91	102.00		100.00		101.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.36		2.29		2.34	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.34 >		1.38 >		1.37 >	
SGOT	0-35 (U/L)	18/05/91	16.00		21.00		21.00	
GAMMA GT	5-23 (U/L)	18/05/91	30.00 >		31.00 >		28.00 >	
LDH	70-170 (U/L)	18/05/91	182.00 >		185.00 >		178.00 >	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	809.00 >>		770.00 >>		775.00 >>	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	5.00		6.40		4.90	
UREA	2.5-7.5 (MMOL/L)	18/05/91	5.70		6.00		4.90	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.07		0.08		0.08	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.23		0.20		0.21	
TOT. BILIRUBIN	0-17 (UMOL/L)	18/05/91	10.00		10.00		9.00	
DIR. BILIRUBIN	0-5 (UMOL/L)	18/05/91	2.00		2.00		3.00	
TOT. PROTEINS	68-83 (G/L)	18/05/91	68.00		65.00 <		67.00 <	
ALBUMINE	36-49 (G/L)	18/05/91	46.00		46.00		45.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	7.00		6.70		6.60	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	1.40		1.00		1.70	
TSH	0.5-6.5 (MIU/L)	18/05/91	3.19					
T4	86-148 (NMOL/L)	18/05/91	89.00					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015

Listing No.: 18.0

9550082

LABORATORY DATA

Centre: 15 Patient: 419 Treatment: Placebo Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/04/92		19/05/92		09/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	18/05/91	14.10		14.00		14.50	
HT	0.35-0.47 (L/L)	18/05/91	0.41		0.41		0.43	
RBC	3.9-5.6 (10 ¹² /L)	18/05/91	4.66		4.62		4.79	
WBC	3.5-12 (10 ⁹ /L)	18/05/91	6.30		7.70		7.60	
WBC: N	2.5-8 (10 ⁹ /L)	18/05/91	3.90		5.90		5.10	
WBC: L	1.2-4 (10 ⁹ /L)	18/05/91	2.10		1.30		2.10	
WBC: E	0-0.5 (10 ⁹ /L)	18/05/91	0.00		0.30		0.20	
WBC: M	0.1-1.1 (10 ⁹ /L)	18/05/91	0.30		0.20		0.20	
WBC: B	0-0.1 (10 ⁹ /L)	18/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ⁹ /L)	18/05/91	208.00		225.00		207.00	
NA+	135-145 (MMOL/L)	18/05/91	138.00		139.00		136.00	
K+	3.5-4.5 (MMOL/L)	18/05/91	4.00		3.70		3.70	
CL-	95-105 (MMOL/L)	18/05/91	101.00		99.00		103.00	
Ca++	2.25-2.75 (MMOL/L)	18/05/91	2.27		2.18 <		2.34	
PO4--	0.6-1.3 (MMOL/L)	18/05/91	1.28		1.28		1.25	
SGOT	0-35 (U/L)	18/05/91	14.00		8.00		14.00	
GAMMA GT	5-23 (U/L)	18/05/91	18.00		18.00		18.00	
LDH	70-170 (U/L)	18/05/91	130.00		111.00		117.00	
ALK. PHOSPH.	18-70 (U/L)	18/05/91	45.00		42.00		38.00	
GLUCOSE	3.3-6.7 (MMOL/L)	18/05/91	4.50		5.00		4.90	
UREA	2.5-7.5 (MMOL/L)	18/05/91	5.60		4.90		5.30	
CREATININE	0.04-0.12 (MMOL/L)	18/05/91	0.08		0.07		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	18/05/91	0.25		0.23		0.23	
TOT BILIRUBIN	0-17 (UMOL/L)	18/05/91	8.00		7.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	18/05/91	2.00		1.00		2.00	
TOT. PROTEINS	68-85 (G/L)	18/05/91	71.00		68.00		73.00	
ALBUMINE	36-49 (G/L)	18/05/91	50.00 >		48.00		51.00 >	
TOT. CHOLEST.	3-8.5 (MMOL/L)	18/05/91	5.70		5.80		6.30	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	18/05/91	0.80		2.40 >>		0.90	
TSH	0.5-6.5 (MIU/L)	18/05/91	0.56					
T4	86-148 (NMOL/L)	18/05/91	108.00					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific Gravity	Albumin	Sugar	HBC
1	1	Imipramine	Female	Evaluated	10/04/91	22/05/91	43	Screen	10/04/91	1 Not done	Absent	Absent	Absent
								Day 21	01/05/91	22 Not done	Absent	Not done	Not done
								Day 42	22/05/91	43 Not done	Present	Absent	Absent
2	2	Reboxetine	Male	Without screen	15/04/91	27/05/91	43	Screen	11/04/91	0 Not done	Absent	Absent	Not done
								Day 21	06/05/91	22 Not done	Absent	Not done	Not done
								Day 42	27/05/91	43 Not done	Absent	Present	Present
3	3	Imipramine	Male	Without screen	06/05/91	16/06/91	42	Screen	02/05/91	0 Not done	Absent	Absent	Not done
								Day 21	27/05/91	22 Not done	Absent	Absent	Present
								Day 42	17/06/91	43 Not done	Not done	Absent	Not done
4	4	Placebo	Male	Evaluated	04/06/91	16/07/91	43	Screen	04/06/91	1 Not done	Present	Absent	Present
								Day 21	25/06/91	22 Not done	Not done	Absent	Present
								Day 42	16/07/91	43 Not done	Not done	Absent	Present
5	5	Reboxetine	Female	Evaluated	12/06/91	02/07/91	21	Screen	12/06/91	1 Not done	Not done	Absent	Present
								Day 21	02/07/91	21 Not done	Not done	Absent	Present
								Day 42	02/07/91	21 Not done	Not done	Absent	Present
6	6	Placebo	Female	Evaluated	23/05/91	05/07/91	44	Screen	23/05/91	1 Not done	Present	Absent	Present
								Day 21	13/06/91	22 Not done	Not done	Absent	Present
								Day 42	08/07/91	47 Not done	Not done	Absent	Present
7	7	Reboxetine	Female	Evaluated	27/08/91	08/10/91	43	Screen	27/08/91	1 Not done	Not done	Absent	Present
								Day 21	17/09/91	23 Not done	Not done	Absent	Present
								Day 42	08/10/91	43 Not done	Absent	Absent	Present
8	8	Placebo	Male	Evaluated	05/09/91	19/10/91	45	Screen	05/09/91	1 Not done	Not done	Absent	Present
								Day 21	28/09/91	24 Not done	Absent	Absent	Present
								Day 42	19/10/91	45 Not done	Absent	Absent	Present
9	9	Reboxetine	Female	Without screen	27/11/91	06/01/92	41	Screen	27/11/91	1 Not done	Not done	Present	Not done
								Day 21	18/12/91	22 Not done	Absent	Absent	Present
								Day 42	06/01/92	41 Not done	Absent	Absent	Present
10	10	Placebo	Male	Evaluated	24/09/91	04/11/91	42	Screen	04/09/91	0 Not done	Absent	Absent	Present
								Day 21	15/10/91	22 Not done	Present	Absent	Present
								Day 42	04/11/91	42 Not done	Absent	Absent	Present

(*) days of treatment

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0
 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test								
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	MBC	
1	11	Imipramine	Female	Only screening	10/10/91	13/10/91	4	Screen	10/10/91	1	Normal	Absent	Absent	Absent	Absent	Absent
	12	Imipramine	Female	Evaluated	18/10/91	30/11/91	44	Screen Day 21 Day 42	18/10/91 15/11/91 05/12/91	1 29 49	Not done Not done Not done	Not done Present Absent	Present Absent Absent	Present Present Present	Present Present Present	Present Present Present
	412	Reboxetine	Male	Evaluated	13/11/91	23/12/91	41	Screen Day 21 Day 42	12/11/91 05/12/91 23/12/91	0 23 41	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present	Present Present Present
	413	Placebo	Male	Evaluated	09/12/91	20/01/92	43	Screen Day 21 Day 42	03/12/91 30/12/91 20/01/92	0 22 43	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present	Present Present Present
	414	Imipramine	Female	Only screening	22/01/92	29/01/92	8	Screen	19/01/92	0	Not done	Absent	Absent	Absent	Present	Present
	415	Imipramine	Male	Evaluated	14/01/92	27/02/92	45	Screen Day 21 Day 42	14/01/92 06/02/92 27/02/92	1 24 45	Not done Not done Not done	Absent Present Absent	Absent Present Present	Present Present Present	Present Present Present	Present Present Present
	416	Reboxetine	Female	Only screening	17/01/92	28/01/92	12	Screen	20/01/92	4	Not done	Absent	Absent	Absent	Present	Present
	421	Imipramine	Male	Evaluated	27/02/92	09/04/92	43	Screen Day 21 Day 42	26/02/92 19/03/92 09/04/92	0 22 43	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Present Present Absent	Present Present Absent	Present Present Absent
	422	Imipramine	Male	Evaluated	05/08/92	17/09/92	44	Screen Day 21 Day 42	04/08/92 26/08/92 17/09/92	0 22 44	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Present Not done	Absent Present Not done	Absent Present Not done
2/1	49	Placebo	Female	Evaluated	18/05/91	28/06/91	42	Screen Day 21 Day 42	16/05/91 08/06/91 29/06/91	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	50	Reboxetine	Female	Evaluated	27/12/91	06/02/92	42	Screen Day 21	24/12/91 16/01/92	0 21	Normal Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent

(*) days of treatment

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0
 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test					
										Specific gravity	Albumin	Sugar	RBC		
2/1	50	Reboxetine	Female	Evaluated	27/12/91	06/02/92	42	Day 42	06/02/92	42	Normal	Present	Absent	Absent	Absent
	51	Imipramine	Female	Evaluated	02/02/92	15/03/92	43	Screen Day 21 Day 42	28/01/92 24/02/92 16/03/92	0 23 44	Normal Normal Normal	Absent Present Absent	Absent Absent Absent	Absent Absent Absent	
2/2	43	Imipramine	Female	Only screening	18/04/91	16/05/91	29	Screen Day 28	11/04/91 13/05/91	0 26	Not done Not done	Present Not done	Absent Not done	Present Not done	
	44	Imipramine	Female	Evaluated	19/07/91	29/08/91	42	Screen Day 21 Day 42	12/07/91 09/08/91 28/08/91	0 22 41	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	45	Reboxetine	Female	Evaluated	08/09/91	20/10/91	43	Screen Day 21 Day 42	27/08/91 30/09/91 21/10/91	0 23 44	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
1-0	46	Placebo	Female	Evaluated	26/09/91	23/10/91	28	Screen Day 28	18/09/91 23/10/91	0 28	Not done Normal	Absent Absent	Absent Absent	Absent Absent	
0	47	Placebo	Female	Without Urinal	24/03/92	04/05/92	42	Screen Day 21 Day 42	13/03/92 14/04/92 05/05/92	0 22 43	Normal Normal Normal	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	
	48	Reboxetine	Female	Without Urinal	07/04/92	19/05/92	43	Screen Day 21 Day 42	03/04/92 28/04/92 20/05/92	0 22 44	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	
2/3	36/A	Imipramine	Male	Without screen	07/03/91	17/04/91	42	Day 21 Day 42	22/03/91 08/04/91	16 33	Not done Not done	Absent Absent	Absent Absent	Present Present	
	37	Reboxetine	Female	Evaluated	27/03/91	07/05/91	42	Screen Day 21 Day 42	18/03/91 16/04/91 13/05/91	0 21 48	Normal Not done Not done	Present Not done Present	Absent Not done Absent	Absent Not done Absent	
	38	Placebo	Male	Evaluated	14/08/91	25/09/91	43	Screen Day 21 Day 42	10/08/91 09/09/91 26/09/91	0 27 44	Not done Not done Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	

(*): days of treatment

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0
URINALYSIS

9550082

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test				
										Specific gravity	Albumin	Sugar	RBC	
2/3	39	Imipramine	Female	Evaluated	10/08/91	20/09/91	42	Screen	06/08/91	0 Not done	Absent	Absent	Present	Present
								Day 21	30/08/91	21 Not done	Absent	Absent	Absent	Absent
								Day 42	20/09/91	42 Not done	Not done	Not done	Not done	Not done
40	40	Reboxetine	Female	Evaluated	24/10/91	04/12/91	42	Screen	24/10/91	1 Not done	Present	Absent	Absent	
								Day 21	15/11/91	23 Normal	Absent	Absent	Absent	
								Day 42	05/12/91	43 Normal	Present	Absent	Absent	
41	41	Placebo	Male	Evaluated	03/10/91	13/11/91	42	Screen	10/10/91	8 Normal	Absent	Absent	Present	
								Day 21	29/10/91	27 Not done	Absent	Absent	Absent	
								Day 42	19/11/91	48 Normal	Absent	Absent	Present	
42	42	Imipramine	Female	Evaluated	19/05/92	30/06/92	43	Screen	03/05/92	0 Normal	Absent	Absent	Present	
								Day 21	06/06/92	19 Not done	Present	Absent	Absent	
								Day 42	30/06/92	43 Not done	Present	Absent	Present	
2/4	31	Placebo	Male	Evaluated	26/03/91	05/05/91	41	Screen	22/03/91	0 Normal	Absent	Absent	Absent	
								Day 21	15/04/91	21 Not done	Not done	Not done	Not done	
								Day 42	30/04/91	36 Normal	Absent	Absent	Absent	
32	32	Reboxetine	Male	Evaluated	26/10/91	06/12/91	42	Screen	17/10/91	0 Normal	Absent	Absent	Absent	
								Day 21	15/11/91	21 Normal	Absent	Absent	Absent	
								Day 42	06/12/91	42 Normal	Absent	Absent	Absent	
33	33	Imipramine	Male	Evaluated	29/05/91	10/07/91	43	Screen	27/05/91	0 Normal	Absent	Absent	Absent	
								Day 21	19/06/91	22 Not done	Not done	Not done	Not done	
								Day 42	10/07/91	43 Normal	Absent	Absent	Absent	
34	34	Placebo	Female	Without screen	17/04/92	28/05/92	42	Screen	11/04/92	0 Not done	Not done	Not done	Not done	
								Day 21	12/05/92	26 Normal	Absent	Present	Absent	
								Day 42	25/05/92	39 Not done	Not done	Not done	Not done	
35	35	Reboxetine	Female	Evaluated	15/09/92	26/10/92	42	Screen	08/09/92	0 Normal	Absent	Absent	Present	
								Day 21	03/10/92	19 Normal	Absent	Absent	Present	
								Day 42	27/10/92	43 Normal	Absent	Absent	Present	
36	36	Imipramine	Female	Only screening	12/02/92	24/03/92	42	Screen	05/02/92	0 Normal	Absent	Present	Absent	

(*): days of treatment

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5

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific gravity	Albumin	Sugar	RBC
2/4	36	Imipramine	Female	Only screening	12/02/92	24/03/92	42	Day 21 Day 42	04/03/92 25/03/92	22 Normal 43 Normal	Absent Absent	Absent Absent	Not done Not done
2/5	73	Placebo	Male	Without screening	07/02/92	20/03/92	43	Screen Day 21 Day 42	05/02/92 02/03/92 24/03/92	0 Not done 25 Not done 47 Not done	Not done Absent Absent	Not done Absent Absent	Not done Present Present
74	74	Reboxetine	Male	Only screening	21/06/92	01/08/92	42	Screen Day 21 Day 42	14/06/92 11/07/92 01/08/92	0 Not done 21 Missing 42 Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done
75	75	Imipramine	Male	Without Urinal	11/09/92	22/10/92	42	Screen Day 21 Day 42	04/09/92 01/10/92 22/10/92	0 Not done 21 Not done 42 Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done
76	76	Imipramine	Female	Without screening	15/09/92	26/10/92	42	Screen Day 21 Day 42	12/09/92 02/10/92 28/10/92	0 Not done 18 Not done 44 Not done	Absent Not done Absent	Absent Not done Absent	Not done Not done Present
77	77	Placebo	Male	Without Urinal	22/09/92	02/11/92	42	Screen Day 21 Day 42	16/09/92 13/10/92 30/10/92	0 Not done 22 Not done 39 Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
78	78	Reboxetine	Female	Without Urinal	10/10/92	13/11/92	35	Screen Day 21	01/10/92 29/10/92	0 Not done 20 Not done	Not done Not done	Not done Not done	Not done Not done
2/6	55	Reboxetine	Female	Without Urinal	12/06/92	23/07/92	42	Screen Day 21 Day 42	15/06/92 03/07/92 20/07/92	4 Not done 22 Not done 39 Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
56	56	Reboxetine	Female	Without Urinal	12/06/92	23/07/92	42	Screen Day 21 Day 42	15/06/92 03/07/92 24/07/92	4 Not done 22 Not done 43 Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
57	57	Imipramine	Female	Without Urinal	05/05/92	15/06/92	42	Screen Day 21 Day 42	30/04/92 26/05/92 15/06/92	0 Not done 22 Not done 42 Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done

(*) days of treatment

9550082

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test						
										Specific gravity	Albumin	Sugar	RBC	MBC	Urea	Cr
2/6	58	Placebo	Female	Without Urinal	18/05/92	29/06/92	43	Screen Day 21 Day 42	18/05/92 09/06/92 24/06/92	1 23 38	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
	59	Placebo	Male	Without Urinal	27/05/92	23/06/92	28	Screen Day 21 Day 28	29/05/92 17/06/92 26/06/92	3 22 31	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
	60	Imipramine	Female	Without Urinal	12/05/92	22/06/92	42	Screen Day 21 Day 42	06/06/92 02/06/92 23/06/92	0 22 43	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
3/1	61	Imipramine	Male	Evaluated	05/03/91	08/04/91	35	Screen Day 21	04/03/91 03/04/91	0 30	Not done Not done	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	62	Imipramine	Female	Evaluated	16/04/91	26/05/91	41	Screen Day 21 Day 42	17/04/91 06/05/91 27/05/91	2 21 42	Normal Not done Normal	Absent Absent Absent	Absent Present Present	Absent Present Present	Absent Present Present	Absent Present Present
	63	Placebo	Male	Evaluated	13/05/91	23/06/91	42	Screen Day 21 Day 42	10/05/91 03/06/91 22/06/91	0 22 41	Normal Normal Not done	Absent Absent Absent	Absent Present Present	Absent Present Present	Absent Present Present	Absent Present Present
	64	Placebo	Female	Without Urinal	14/03/91	24/04/91	42	Screen Day 21	08/03/91 03/04/91	0 21	Not done Not done	Absent Absent	Absent Absent	Not done Not done	Not done Not done	Not done Not done
	65	Reboxetine	Male	Evaluated	16/09/91	27/10/91	42	Screen Day 21 Day 42	11/09/91 07/10/91 28/10/91	0 22 43	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	66	Reboxetine	Male	Without Urinal	10/06/91	21/07/91	42	Screen Day 21 Day 42	06/06/91 01/07/91 22/07/91	0 22 43	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
	139	Imipramine	Male	Only screening	03/09/91	12/09/91	10	Screen	03/09/91	1	Not done	Absent	Absent	Absent	Absent	Absent
	140	Placebo	Male	Only screening	12/09/91	23/10/91	42	Screen Day 21	10/09/91 03/10/91	0 22	Not done Not done	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent

(*) days of treatment

9550082

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7

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0
URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test						
					Start date	End date	Days	Assessment	Date	(*) Specific gravity	Albumin	Sugar	RBC	NBC
3/1	141	Placebo	Female	Evaluated	03/10/91	14/11/91	43	Screen Day 21 Day 42	26/09/91 23/10/91 14/11/91	0 Not done 21 Not done 43 Not done	Absent Absent Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent
	142	Imipramine	Female	Only screening	18/11/91	08/12/91	21	Screen	14/11/91	0 Normal	Absent	Absent	Present	Present
	143	Reboxetine	Female	Without screen	15/04/92	20/05/92	36	Screen Day 21 Day 35	14/04/92 06/05/92 20/05/92	0 Not done 22 Not done 36 Not done	Absent Not done Absent	Absent Not done Absent	Not done Not done Absent	Not done Not done Absent
	144	Reboxetine	Female	Evaluated	09/06/92	22/07/92	44	Screen Day 42	04/06/92 21/07/92	0 Not done 43 Not done	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	451	Reboxetine	Female	Only screening	20/01/92	01/02/92	13	Screen	16/01/92	0 Not done	Absent	Absent	Absent	Absent
	452	Placebo	Male	Only screening	22/01/92	04/03/92	43	Screen Day 21 Day 42	15/01/92 12/02/92 09/03/92	0 Not done 22 Not done 48 Not done	Absent Absent Not done	Absent Not done Not done	Absent Not done Not done	Absent Not done Not done
	453	Imipramine	Female	Evaluated	29/01/92	10/03/92	42	Screen Day 21 Day 42	28/01/92 19/02/92 11/03/92	0 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Not done Absent	Present Not done Absent	Present Not done Absent
	454	Reboxetine	Male	Without screen	17/02/92	01/04/92	45	Screen Day 21 Day 42	13/02/92 09/03/92 01/04/92	0 Not done 22 Not done 45 Not done	Absent Absent Absent	Absent Absent Absent	Not done Absent Absent	Not done Absent Absent
	455	Placebo	Female	Without screen	11/03/92	22/04/92	43	Screen Day 21 Day 42	03/03/92 01/04/92 22/04/92	0 Not done 22 Not done 43 Not done	Absent Absent Not done	Absent Absent Not done	Not done Absent Not done	Not done Absent Not done
	456	Imipramine	Female	Only screening	25/03/92	03/04/92	10	Screen	18/03/92	0 Not done	Absent	Absent	Absent	Absent
3/2	65/A	Reboxetine	Female	Without Urinal	29/01/91	11/03/91	42	Screen Day 21 Day 42	25/01/91 19/02/91 12/03/91	0 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done

1974

(*) days of treatment

9550082

9550082

8

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test						
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC
3/3	67	Placebo	Male	Evaluated	18/07/91	28/08/91	42	Screen	16/07/91	0 Normal	Absent	Absent	Present	Present
									07/08/91	21 Normal	Present	Present	Present	
									28/08/91	42 Normal	Absent	Absent	Absent	
68	Reboxetine	Male	Only screening	21/01/92	02/03/92	42	Screen	14/01/92	0 Normal	Absent	Absent	Absent	Absent	
								10/02/92	21 Normal	Absent	Absent	Not done		
								02/03/92	42 Not done	Absent	Absent	Not done		
69	Placebo	Male	Evaluated	04/02/92	16/03/92	42	Screen	31/01/92	0 Normal	Absent	Absent	Absent	Absent	
								24/02/92	21 Not done	Absent	Absent	Absent		
								16/03/92	42 Normal	Absent	Absent	Present		
70	Imipramine	Male	Only screening	15/04/92	26/05/92	42	Screen	10/04/92	0 Normal	Absent	Absent	Present	Present	
								05/05/92	21 Not done	Absent	Absent	Not done		
								26/05/92	42 Not done	Absent	Absent	Not done		
71	Imipramine	Female	Only screening	16/04/92	27/05/92	42	Screen	14/04/92	0 Normal	Absent	Absent	Present	Present	
								06/05/92	21 Not done	Absent	Absent	Not done		
								27/05/92	42 Normal	Absent	Absent	Not done		
72	Reboxetine	Male	Only screening	25/07/92	04/09/92	42	Screen	21/07/92	0 Normal	Absent	Absent	Absent	Present	
								14/08/92	21 Not done	Absent	Absent	Not done		
								04/09/92	42 Not done	Absent	Absent	Not done		
79	Imipramine	Female	Without Urinal	04/05/91	15/06/91	43	Screen	01/05/91	0 Not done	Not done	Not done	Not done	Not done	
								24/05/91	21 Not done	Not done	Not done	Not done		
								19/06/91	47 Not done	Not done	Not done	Not done		
80	Imipramine	Male	Without Urinal	01/09/91	24/09/91	24	Screen	31/08/91	0 Not done	Not done	Not done	Not done	Not done	
								15/05/91	0 Not done	Absent	Absent	Not done		
								04/06/91	19 Not done	Absent	Absent	Present		
81	Reboxetine	Female	Without screen	17/05/91	27/06/91	42	Screen	04/06/91	19 Not done	Absent	Absent	Absent	Not done	
								28/06/91	43 Normal	Absent	Absent	Absent		
								14/06/91	0 Not done	Absent	Absent	Absent		
82	Placebo	Male	Without Urinal	17/06/91	28/07/91	42	Screen	08/07/91	22 Not done	Absent	Absent	Absent	Not done	
								29/07/91	43 Not done	Absent	Absent	Absent		

(*) days of treatment

9550082

9

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period		Days	Assessment	Date	Urinalysis test					
					Start date	End date				Specific gravity	Albunin	Sugar	RBC	MBC	
3/4	83	Placebo	Male	Only screening	17/06/91	24/06/91	8	Screen	13/06/91	0	Not done	Absent	Absent	Absent	Absent
	84	Reboxetine	Female	Only screening	09/10/91	23/11/91	46	Screen Day 21 Day 42	08/10/91 31/10/91 12/11/91	0 23 35	Normal Not done Not done	Absent Not done Not done	Absent Not done Not done	Absent Not done Not done	
	85	Imipramine	Female	Without Urinal	29/10/91	08/12/91	41	Screen Day 21 Day 42	26/10/91 19/11/91 09/12/91	0 22 42	Not done Not done Not done	Absent Absent Absent	Absent Present Present	Not done Not done Not done	
	86	Imipramine	Male	Evaluated	03/12/91	15/01/92	44	Screen Day 21 Day 42	02/12/91 24/12/91 15/01/92	0 22 44	Normal Not done Not done	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent	
	87	Placebo	Female	Only screening	09/12/91	19/01/92	42	Screen Day 21 Day 42	07/12/91 27/12/91 30/01/92	0 19 43	Normal Not done Not done	Absent Absent Absent	Absent Not done Not done	Absent Not done Not done	
	88	Placebo	Male	Evaluated	29/03/92	08/05/92	47	Screen Day 21 Day 42	18/03/92 22/04/92 09/05/92	0 31 48	Normal Normal Not done	Absent Absent Not done	Absent Absent Not done	Absent Absent Not done	
	89	Reboxetine	Female	Evaluated	26/03/92	06/05/92	42	Screen Day 21 Day 42	23/03/92 15/04/92 12/05/92	0 21 48	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	90	Reboxetine	Male	Only screening	28/04/92	08/06/92	42	Screen Day 21 Day 42	28/04/92 19/05/92 23/06/92	1 22 57	Not done Not done Not done	Absent Absent Absent	Absent Not done Absent	Absent Not done Not done	
	457	Placebo	Female	Without screen	22/05/92	11/06/92	21	Screen Day 21	18/05/92 10/06/92	0 20	Not done Not done	Not done Absent	Not done Absent	Not done Absent	
	458	Reboxetine	Female	Only screening	26/05/92	09/06/92	15	Screen	18/05/92	0	Not done	Absent	Absent	Absent	
	459	Placebo	Female	Evaluated	02/06/92	13/07/92	42	Screen	29/05/92	0	Not done	Absent	Absent	Absent	

(*) days of treatment

1976

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

10

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0
URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific gravity	Albumin	Sugar	RBC
3/4	459	Placebo	Female	Evaluated	02/06/92	13/07/92	42	Day 21 Day 42	23/06/92 15/07/92	22 Not done 44 Not done	Absent Absent	Absent Absent	Absent Absent
460	460	Reboxetine	Male	Only screening	19/08/92	20/08/92	2	Screen	17/08/92	0 Not done	Absent	Absent	Absent
461	461	Imipramine	Female	Without Urinal	17/09/92	24/09/92	8	Screen	15/09/92	0 Normal	Not done	Not done	Not done
462	462	Imipramine	Female	Without Urinal	29/09/92	08/10/92	10	Screen	29/09/92	1 Normal	Not done	Not done	Not done
4/1	91	Imipramine	Female	Only screening	12/10/91	22/11/91	42	Screen Day 21 Day 42	17/10/91 02/11/91 23/11/91	6 Normal 22 Not done 43 Not done	Absent Not done Not done	Absent Not done Not done	Absent Not done Not done
92	92	Reboxetine	Female	Evaluated	07/08/91	17/09/91	42	Screen Day 21 Day 42	03/08/91 28/08/91 18/09/91	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present
93	93	Placebo	Male	Evaluated	03/07/91	16/08/91	45	Screen Day 21 Day 42	29/06/91 24/07/91 14/08/91	0 Normal 22 Normal 43 Not done	Absent Absent Not done	Absent Absent Not done	Present Absent Not done
94	94	Placebo	Female	Evaluated	05/07/91	13/08/91	40	Screen Day 21 Day 42	29/06/91 24/07/91 27/08/91	0 Normal 20 Normal 54 Normal	Absent Absent Absent	Absent Absent Absent	Present Not done Present
95	95	Imipramine	Female	Without screen	03/06/91	16/07/91	44	Screen Day 21 Day 42	09/06/91 28/06/91 17/07/91	7 Not done 26 Not done 45 Not done	Not done Absent Absent	Not done Absent Absent	Not done Present Present
96	96	Reboxetine	Female	Evaluated	04/09/91	16/10/91	43	Screen Day 21 Day 42	30/08/91 25/09/91 25/10/91	0 Normal 22 Normal 52 Normal	Absent Absent Absent	Absent Absent Absent	Present Absent Absent
115	115	Reboxetine	Female	Evaluated	06/05/92	16/06/92	42	Screen Day 21 Day 42	30/04/92 02/06/92 19/06/92	0 Normal 28 Normal 45 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present

(*) days of treatment

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

11

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test								
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	MBC	
4/1	116	Imipramine	Female	Only screening	16/05/92	22/05/92	7	Screen	09/05/92	0	Normal	Absent	Absent	Absent	Absent	Absent
	117	Imipramine	Female	Evaluated	03/09/91	14/10/91	42	Screen Day 21 Day 42	29/08/91 24/09/91 15/10/91	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Present Absent	Present Present Absent	
	118	Reboxetine	Female	Without screen	23/05/92	03/07/92	42	Screen Day 21 Day 42	15/05/92 13/06/92 04/07/92	0 22 43	Not done Normal Normal	Not done Absent Absent	Not done Absent Absent	Not done Present Present	Not done Present Present	
	119	Placebo	Female	Only screening				Screen	16/03/92		Normal	Absent	Absent	Absent	Absent	
	120	Placebo	Female	Evaluated	31/07/92	11/09/92	43	Screen Day 21 Day 42	04/06/92 21/08/92 22/09/92	0 22 54	Not done Normal Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present	
	145	Imipramine	Female	Evaluated	30/09/92	10/11/92	42	Screen Day 21 Day 42	30/09/92 30/10/92 10/11/92	1 31 42	Not done Normal Not done	Absent Absent Not done	Absent Absent Not done	Present Absent Not done	Present Present Not done	
	146	Placebo	Female	Evaluated	16/09/92	27/10/92	42	Screen Day 21 Day 42	03/08/92 05/10/92 27/10/92	0 20 42	Not done Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	147	Reboxetine	Female	Evaluated	01/09/92	12/10/92	42	Screen Day 21 Day 42	16/07/92 21/09/92 13/10/92	0 21 43	Normal Not done Not done	Absent Absent Absent	Absent Absent Absent	Present Absent Absent	Present Present Present	
	148	Imipramine	Female	Evaluated	26/09/92	06/11/92	42	Screen Day 21 Day 42	11/09/92 20/10/92 10/11/92	0 25 46	Normal Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Present Absent	Absent Present Present	
	149	Reboxetine	Male	Evaluated	30/09/92	10/11/92	42	Screen Day 21 Day 42	22/09/92 21/10/92 18/11/92	0 22 50	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	150	Placebo	Male	Evaluated	30/09/92	10/11/92	42	Screen Day 21	23/09/92 15/10/92	0 16	Normal Normal	Absent Absent	Absent Absent	Absent Present	Absent Present	

(*) days of treatment

9550082

1978

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0
 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test						
					Start date	End date	Days Assessment	Date	Specific gravity	Albumin	Sugar	RBC	MBC	
4/1	150	Placebo	Male	Evaluated	30/09/92	10/11/92	42 Day 42	10/11/92	42 Normal	Absent	Absent	Present	Present	Present
4/2	93/A	Placebo	Male	Without Urinal	22/02/91	04/04/91	42 Screen Day 21	23/02/91 18/03/91	2 25	Not done Not done	Not done Not done	Not done Not done	Not done Not done	Not done Not done
4/3	99/A	Placebo	Male	Without Urinal	27/03/91	07/05/91	42 Day 21 Day 42	10/04/91 04/05/91	15 39	Not done Not done	Not done Not done	Not done Not done	Not done Not done	Not done Not done
4/3	104	Reboxetine	Male	Without Urinal	22/05/91	02/07/91	42 Day 21	04/06/91	14	Not done	Not done	Not done	Not done	Not done
4/3	97	Placebo	Male	Evaluated	17/04/91	28/05/91	42 Screen Day 21 Day 42	11/04/91 07/05/91 28/05/91	0 21 42	Normal Not done Normal	Present Not done Present	Absent Not done Absent	Present Not done Present	Present Not done Present
4/3	98	Reboxetine	Female	Evaluated	20/06/91	21/07/91	32 Screen Day 21 Day 35	17/06/91 19/07/91 02/08/91	0 24 44	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
4/3	99	Placebo	Female	Only screening	08/08/91	15/08/91	8 Screen	07/08/91	0	Normal	Absent	Absent	Present	Present
4/3	100	Imipramine	Female	Evaluated	27/11/91	17/12/91	21 Screen Day 21	22/11/91 08/01/92	0 43	Normal Normal	Absent Absent	Absent Absent	Present Present	Present Present
4/4	101	Imipramine	Male	Evaluated	17/03/92	27/04/92	42 Screen Day 21 Day 42	16/03/92 06/04/92 27/04/92	0 21 42	Normal Not done Normal	Absent Not done Present	Present Not done Present	Present Not done Present	Present Not done Present
4/4	109	Reboxetine	Female	Only screening	08/06/91	19/07/91	42 Screen Day 21 Day 42	03/06/91 27/06/91 20/08/91	0 20 74	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Present Not done Not done	Present Not done Not done
4/4	110	Imipramine	Male	Evaluated	15/06/91	26/07/91	42 Screen Day 21 Day 42	11/06/91 04/07/91 26/07/91	0 20 42	Normal Normal Normal	Not done Present Absent	Absent Present Absent	Absent Present Present	Present Present Present
4/4	111	Imipramine	Male	Evaluated	04/07/91	14/08/91	42 Screen Day 21	24/06/91 24/07/91	0 21	Normal Normal	Present Absent	Absent Absent	Present Present	Present Present

9550082

(*): days of treatment

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0
URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test										
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	MBC			
4/4	111	Imipramine	Male	Evaluated	04/07/91	14/08/91	42	Day 42	14/08/91	42	Not done	Not done	Not done	Not done	Not done	Not done	Not done	
	112	Placebo	Male	Evaluated	10/07/91	20/08/91	42	Screen Day 21 Day 42	10/07/91 31/07/91 20/08/91	1 22 42	Normal Normal Normal	Present Present Present	Absent Present Present	Absent Present Present	Present Present Present	Present Present Present	Not done Not done Not done	
	113	Reboxetine	Male	Evaluated	31/08/91	11/10/91	42	Screen Day 21 Day 42	26/08/91 23/09/91 11/10/91	0 24 42	Normal Normal Normal	Absent Present Present	Absent Present Present	Absent Present Present	Present Present Present	Present Present Present	Present Present Present	
	114	Placebo	Female	Without Urinal	20/11/91	31/12/91	42	Screen Day 0 Day 21 Day 42	07/11/91 07/11/91 10/12/91 31/12/91	0 0 21 42	Normal Normal Normal Normal	Present Present Not done Not done	Absent Present Not done Not done	Absent Present Not done Not done	Present Present Not done Not done	Present Present Not done Not done	Not done Not done Not done Not done	
1300	175	Imipramine	Female	Without screen	19/02/92	25/03/92	42	Screen Day 21 Day 42	05/02/92 04/03/92 25/03/92	0 21 42	Normal Normal Normal	Present Present Present	Absent Present Present	Absent Present Present	Absent Present Present	Not done Not done Not done	Not done Not done Not done	
	176	Placebo	Female	Without Urinal	14/03/92	08/04/92	26	Screen Day 21 Day 28	13/03/92 06/04/92 09/04/92	0 24 27	Normal Normal Not done	Not done Present Not done	Absent Present Not done	Not done Present Not done	Not done Present Not done	Not done Present Not done	Not done Not done Not done	
	177	Imipramine	Female	Evaluated	28/04/92	11/05/92	14	Screen Day 21	22/04/92 27/05/92	0 30	Normal Normal	Present Present	Absent Present	Absent Present	Absent Present	Absent Present	Absent Present	
	178	Reboxetine	Female	Evaluated	28/04/92	08/06/92	42	Screen Day 21 Day 42	21/04/92 18/05/92 09/06/92	0 21 43	Normal Normal Normal	Present Present Present	Absent Present Present	Absent Present Present	Absent Present Present	Absent Present Present	Absent Present Present	
	179	Placebo	Female	Only screening	11/09/92	29/09/92	19	Screen Day 21	08/09/92 30/09/92	0 20	Normal Normal	Present Present	Absent Present	Absent Present	Present Present	Present Present	Present Present	Not done Not done
	180	Reboxetine	Male	Without screen	07/10/92	17/11/92	42	Screen Day 21 Day 42	30/09/92 27/10/92 17/11/92	0 21 42	Not done Normal Normal	Not done Present Present	Not done Present Present	Not done Present Present	Not done Present Present	Not done Present Present	Not done Present Present	
5/1	127	Reboxetine	Male	Without Urinal	06/06/91	17/07/91	42	Screen	03/06/91	0	Not done	Not done	Not done	Not done	Not done	Not done	Not done	

(*) days of treatment

9550082

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test								
					Start date	End date	Days	Assessment	Date	(*) Specific Gravity	Albumin	Sugar	RBC	HBC		
S/1	127	Reboxetine	Male	Without Urinal	06/06/91	17/07/91	42	Day 21	27/06/91	22	Not done	Absent	Absent	Not done	Not done	
								Day 42	18/07/91	43	Not done	Absent	Absent	Not done	Not done	
	128	Reboxetine	Female	Without Urinal	14/06/91	25/07/91	42	Screen	10/06/91	0	Not done	Not done	Not done	Not done	Not done	
								Day 21	05/07/91	22	Not done	Absent	Absent	Not done	Not done	
	129	Placebo	Male	Evaluated	24/12/91	03/02/92	42	Screen	23/12/91	0	Not done	Absent	Absent	Absent	Absent	
								Day 21	13/01/92	21	Not done	Absent	Absent	Absent	Absent	
	130	Placebo	Male	Evaluated	05/03/92	15/04/92	42	Screen	25/02/92	0	Not done	Absent	Absent	Absent	Absent	
								Day 21	15/04/92	21	Not done	Absent	Absent	Absent	Absent	
	S/2	131	Imipramine	Female	Evaluated	21/03/92	30/04/92	41	Screen	20/03/92	0	Not done	Absent	Absent	Absent	Absent
									Day 21	10/04/92	21	Not done	Absent	Absent	Absent	Absent
		132	Imipramine	Male	Evaluated	25/06/92	06/08/92	43	Screen	23/06/92	0	Normal	Absent	Absent	Absent	Absent
									Day 21	16/07/92	22	Normal	Absent	Absent	Absent	Absent
121		Imipramine	Female	Without screen	20/12/91	27/01/92	39	Screen	13/12/91	0	Not done	Not done	Not done	Not done	Not done	
								Day 21	10/01/92	22	Not done	Not done	Not done	Not done	Not done	
125		Reboxetine	Male	Evaluated	28/01/91	10/03/91	42	Screen	25/01/91	0	Not done	Absent	Absent	Present	Present	
								Day 21	11/02/91	15	Not done	Absent	Absent	Present	Absent	
133		Placebo	Male	Without Urinal	29/11/91	12/12/91	14	Screen	26/11/91	0	Not done	Not done	Not done	Not done	Not done	
								Day 14	13/12/91	15	Not done	Not done	Not done	Not done	Not done	
134		Reboxetine	Female	Evaluated	06/12/91	16/01/92	42	Screen	04/12/91	0	Normal	Absent	Absent	Absent	Absent	
								Day 21	27/12/91	22	Normal	Absent	Absent	Absent	Absent	
								Day 42	16/01/92	42	Not done	Not done	Not done	Not done	Not done	

(*) days of treatment

9550082

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Assessment	Date	Urinalysis test				
					Start date	End date	Days			Specific gravity	Albumin	Sugar	RBC	
5/3	135	Imipramine	Female	Without Urinal	42	Screen	10/01/92	20/02/92	06/01/92	0	Not done	Not done	Not done	Not done
							Day 21	21	Not done	Not done	Not done	Not done	Not done	
							Day 42	42	Not done	Not done	Not done	Not done	Not done	
136	136	Imipramine	Female	Without Urinal	42	Screen	02/03/92	12/04/92	02/03/92	1	Not done	Not done	Not done	Not done
							Day 21	23	Not done	Not done	Not done	Not done	Not done	
							Day 42	43	Not done	Not done	Not done	Not done	Not done	
137	137	Reboxetine	Female	Without Urinal	42	Screen	15/05/92	25/06/92	12/05/92	0	Normal	Not done	Not done	Not done
							Day 21	22	Normal	Not done	Not done	Not done	Not done	
							Day 42	42	Normal	Not done	Not done	Not done	Not done	
138	138	Placebo	Female	Without Urinal	2	Screen	15/05/92	16/05/92	14/05/92	0	Normal	Not done	Not done	Not done
							21/01/92	28/01/92	15/01/92	0	Normal	Absent	Absent	Present
							Day 7	7	Normal	Absent	Absent	Present	Present	
152	152	Reboxetine	Female	Evaluated	44	Screen	24/02/92	07/04/92	19/02/92	0	Normal	Absent	Absent	Present
							Day 21	22	Normal	Absent	Absent	Present	Present	
							Day 42	48	Normal	Absent	Absent	Present	Present	
153	153	Reboxetine	Male	Evaluated	43	Screen	18/03/91	29/04/91	04/03/91	0	Normal	Absent	Absent	Present
							Day 21	22	Normal	Absent	Absent	Present	Present	
							Day 42	47	Normal	Absent	Absent	Present	Present	
154	154	Imipramine	Female	Only screening	8	Screen	30/03/92	06/04/92	25/03/92	0	Normal	Absent	Absent	Present
							08/07/92	04/08/92	02/07/92	0	Normal	Absent	Absent	Present
							Day 28	28	Normal	Absent	Absent	Present	Present	
155	155	Placebo	Male	Evaluated	42	Screen	08/09/92	19/10/92	03/09/92	0	Normal	Absent	Absent	Present
							Day 21	22	Not done	Not done	Not done	Not done	Not done	
							Day 42	43	Not done	Not done	Not done	Not done	Not done	
6/2	157	Reboxetine	Male	Evaluated	42	Screen	30/04/91	10/06/91	29/04/91	0	Not done	Absent	Absent	Present
							Day 21	22	Not done	Absent	Absent	Absent	Absent	
							Day 42	42	Normal	Absent	Absent	Absent	Present	

(*) days of treatment

9550082

16

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test							
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	MBC
6/2	158	Imipramine	Female	Without Urinal	24/11/91	05/01/92	43	Day 21 Day 42	17/12/91 10/01/92	24 48	Not done Not done	Not done Not done	Not done Not done	Not done Not done	Not done Not done
	159	Imipramine	Male	Evaluated	14/07/91	24/08/91	42	Screen Day 21 Day 42	11/07/91 07/08/91 29/08/91	0 25 47	Normal Not done Normal	Present Absent Absent	Absent Present Present	Present Present Present	Present Present Present
	160	Placebo	Male	Evaluated	24/11/91	04/01/92	42	Screen Day 21 Day 42	22/11/91 14/12/91 28/01/92	0 21 66	Not done Not done Not done	Present Present Present	Absent Absent Absent	Present Not done Present	Present Not done Present
	161	Reboxetine	Female	Evaluated	20/02/92	18/03/92	28	Screen Day 21	18/02/92 11/03/92	0 21	Normal Not done	Absent Absent	Absent Absent	Present Present	Present Present
L1 C0 C3	162	Placebo	Male	Only screening	10/07/91	13/07/91	4	Screen	08/07/91	0	Normal	Present	Absent	Present	Present
	169	Imipramine	Female	Evaluated	26/12/91	15/01/92	21	Screen Day 21	09/12/91 15/01/92	0 21	Not done Not done	Present Absent	Absent Absent	Present Present	Present Present
	170	Placebo	Male	Only screening	01/11/91	15/11/91	15	Screen	29/10/91	0	Not done	Absent	Absent	Absent	Absent
	171	Imipramine	Female	Evaluated	22/07/92	01/09/92	42	Screen Day 21 Day 42	20/07/92 11/08/92 16/09/92	0 21 57	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	172	Reboxetine	Female	Evaluated	07/07/92	17/08/92	42	Screen Day 21 Day 42	07/07/92 27/07/92 22/08/92	1 24 47	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Present	Absent Absent Present
	173	Placebo	Male	Evaluated	05/07/92	15/08/92	42	Screen Day 21	26/06/92 25/07/92	0 21	Not done Not done	Absent Absent	Absent Absent	Present Present	Present Present
	174	Reboxetine	Male	Evaluated	11/05/92	21/06/92	42	Screen Day 21 Day 42	06/05/92 01/06/92 27/06/92	0 22 48	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Present Absent Present	Present Present Present

(*) days of treatment

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0
 URINALYSIS

9550082

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test				
										Specific gravity	Albumin	Sugar	RBC	
6/3	163	Reboxetine	Male	Only screening	06/06/91	08/06/91	3	Screen	05/06/91	0 Normal	Absent	Absent	Present	Present
	164	Imipramine	Male	Evaluated	11/10/91	21/11/91	42	Screen Day 21 Day 42	07/10/91 31/10/91 22/11/91	0 Normal 21 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	165	Imipramine	Female	Evaluated	16/10/91	26/11/91	42	Screen Day 21 Day 42	10/10/91 05/11/91 26/11/91	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Present Absent
	166	Reboxetine	Female	Only screening	25/10/91	29/10/91	5	Screen	25/10/91	1 Normal	Present	Absent	Absent	Absent
1984	167	Placebo	Female	Evaluated	18/11/91	27/12/91	40	Screen Day 21 Day 42	16/11/91 09/12/91 27/12/91	0 Normal 22 Not done 40 Normal	Absent Absent Absent	Absent Absent Absent	Absent Present Present	Absent Present Present
	168	Placebo	Female	Evaluated	03/12/91	06/01/92	35	Screen Day 21	26/11/91 23/12/91	0 Normal 21 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	505	Imipramine	Female	Evaluated	03/12/91	17/12/91	15	Screen Day 14	29/11/91 20/12/91	0 Normal 18 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	506	Placebo	Female	Evaluated	08/01/92	19/02/92	43	Screen Day 21 Day 42	06/01/92 29/01/92 19/02/92	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	507	Imipramine	Female	Evaluated	14/01/92	24/02/92	42	Screen Day 21 Day 42	09/01/92 04/02/92 24/02/92	0 Normal 22 Normal 42 Normal	Absent Absent Present	Absent Absent Absent	Absent Absent Present	Present Present Present
	508	Reboxetine	Female	Evaluated	05/02/92	17/03/92	42	Screen Day 21 Day 42	30/01/92 25/02/92 17/03/92	0 Normal 21 Not done 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Present	Absent Absent Present
	509	Placebo	Male	Without screen	24/02/92	06/04/92	43	Screen Day 21	24/02/92 16/03/92	1 Normal 22 Normal	Absent Absent	Absent Absent	Absent Present	Not done Present

(*): days of treatment

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PHARMACIA CNS R&D
REBOXETINE - PROTUCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test				
										Specific gravity	Albumin	Sugar	RBC	
6/3	509	Placebo	Male	Without screen	24/02/92	06/04/92	43	Day 42	06/04/92	43 Normal	Absent	Absent	Present	Present
	510	Reboxetine	Female	Only screening	27/02/92	10/03/92	13	Screen	26/02/92	0 Normal	Absent	Absent	Present	Present
	511	Imipramine	Female	Evaluated	19/03/92	21/04/92	34	Screen Day 21	19/03/92 07/04/92	1 Normal 20 Normal	Absent Absent	Absent Absent	Present Present	Present Present
	512	Placebo	Female	Only screening	01/04/92	01/04/92	1	Screen	27/03/92	0 Normal	Present	Absent	Present	Present
	513	Imipramine	Female	Evaluated	13/05/92	23/06/92	42	Screen Day 21 Day 42	05/05/92 02/06/92 23/06/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
7/02	181	Reboxetine	Male	Evaluated	27/01/92	08/03/92	42	Screen Day 21 Day 42	22/01/92 17/02/92 09/03/92	0 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	182	Placebo	Male	Evaluated	23/11/91	03/01/92	42	Screen Day 21 Day 42	22/11/91 13/12/91 03/01/92	0 Not done 21 Not done 42 Abnormal	Absent Absent Absent	Absent Absent Absent	Absent Present Present	Absent Present Present
1- CO DO CT	183	Imipramine	Male	Evaluated	02/01/92	18/01/92	17	Screen Day 21	30/12/91 22/01/92	0 Not done 21 Not done	Absent Absent	Absent Absent	Present Present	Present Present
	184	Imipramine	Female	Evaluated	27/01/92	08/03/92	42	Screen Day 21 Day 42	23/01/92 17/02/92 09/03/92	0 Abnormal 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Present Present	Absent Present Present
	185	Reboxetine	Male	Evaluated	10/04/92	05/05/92	26	Screen Day 21	09/04/92 30/04/92	0 Normal 21 Normal	Absent Absent	Present Present	Present Present	Present Present
	186	Placebo	Male	Evaluated	16/04/92	27/05/92	42	Screen Day 21 Day 42	15/04/92 06/05/92 27/05/92	0 Normal 21 Not done 42 Not done	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	535	Placebo	Male	Evaluated	15/04/92	26/05/92	42	Screen Day 21	15/04/92 09/05/92	1 Not done 25 Not done	Absent Absent	Absent Absent	Absent Absent	Absent Absent

(*): days of treatment

9550082

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PHARMACIA CNS R2D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0
URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test								
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC	
7/02	535	Placebo	Male	Evaluated	15/04/92	26/05/92	42	Day 42	27/05/92	43	Not done	Absent	Absent	Absent	Absent	Absent
	536	Reboxetine	Female	Evaluated	08/05/92	18/06/92	42	Screen Day 21 Day 42	08/05/92 29/05/92 22/06/92	1 22 46	Net done Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
7/03	187	Imigranine	Female	Only screening	18/02/92	30/03/92	42	Screen Day 21 Day 42	11/02/92 10/03/92 31/03/92	0 22 43	Net done Not done Not done	Absent Not done Not done	Absent Not done Not done	Absent Not done Not done	Absent Not done Not done	
	188	Placebo	Male	Only screening	25/02/92	06/04/92	42	Screen Day 21 Day 42	18/02/92 17/03/92 07/04/92	0 22 43	Net done Not done Not done	Absent Not done Not done	Absent Not done Not done	Present Not done Not done	Absent Not done Not done	
	189	Placebo	Male	Evaluated	25/02/92	06/04/92	42	Screen Day 21 Day 42	18/02/92 17/03/92 07/04/92	0 22 43	Net done Not done Not done	Absent Not done Not done	Absent Not done Not done	Absent Not done Not done	Absent Not done Not done	
1- CO C	190	Reboxetine	Male	Evaluated	28/02/92	09/04/92	42	Screen Day 21 Day 42	21/02/92 20/03/92 10/04/92	0 22 43	Net done Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	191	Imigranine	Female	Only screening	03/03/92	10/04/92	39	Screen Day 21	25/02/92 24/03/92	0 22	Net done Not done	Absent Not done	Absent Not done	Absent Not done	Absent Not done	
	192	Reboxetine	Female	Evaluated	10/03/92	20/04/92	42	Screen Day 21 Day 42	03/03/92 31/03/92 21/04/92	0 22 43	Net done Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	523	Reboxetine	Female	Evaluated	06/05/92	16/06/92	42	Screen Day 21 Day 42	05/05/92 26/05/92 16/06/92	0 21 42	Net done Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	524	Placebo	Female	Evaluated	06/05/92	16/06/92	42	Screen Day 21 Day 42	05/05/92 26/05/92 16/06/92	0 21 42	Net done Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	525	Placebo	Female	Evaluated	06/05/92	16/06/92	42	Screen	05/05/92	0	Net done	Absent	Absent	Absent	Absent	

(*) days of treatment

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0
 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test				
										Specific gravity	Albumin	Sugar	RBC	
7/03	525	Placebo	Female	Evaluated	06/05/92	16/06/92	42	Day 21	26/05/92	21 Not done	Absent	Absent	Absent	Absent
								Day 42	16/06/92	42 Not done	Absent	Absent	Absent	Absent
	526	Reboxetine	Female	Evaluated	06/05/92	16/06/92	42	Screen	05/05/92	0 Not done	Absent	Absent	Absent	Absent
								Day 21	26/05/92	21 Not done	Absent	Absent	Absent	Absent
527	Imipramine	Female	Evaluated	19/05/92	29/06/92	42	Screen	12/05/92	0 Not done	Absent	Absent	Absent	Absent	
							Day 21	09/06/92	22 Not done	Not done	Not done	Not done	Not done	
528	Imipramine	Female	Evaluated	19/05/92	22/06/92	35	Day 42	30/06/92	43 Not done	Absent	Absent	Absent	Absent	
							Screen	12/05/92	0 Not done	Absent	Absent	Absent	Absent	
7/04	193	Placebo	Female	Without Urinal	25/01/92	06/03/92	42	Day 21	25/01/92	1 Normal	Not done	Not done	Not done	
								Day 42	15/02/92	22 Normal	Not done	Not done	Not done	Not done
	194	Reboxetine	Male	Without screen	25/01/92	06/03/92	42	Screen	25/01/92	1 Normal	Not done	Not done	Not done	
								Day 21	15/02/92	22 Normal	Absent	Absent	Absent	Absent
195	Placebo	Female	Evaluated	25/01/92	06/03/92	42	Day 42	07/03/92	43 Normal	Absent	Absent	Absent		
							Screen	25/01/92	1 Normal	Absent	Absent	Absent	Absent	
196	Reboxetine	Female	Evaluated	01/02/92	13/03/92	42	Day 21	22/02/92	22 Normal	Absent	Absent	Absent		
							Day 42	07/03/92	43 Normal	Absent	Absent	Absent	Absent	
197	Imipramine	Male	Evaluated	01/02/92	13/03/92	42	Screen	01/02/92	1 Normal	Absent	Absent	Absent		
							Day 21	22/02/92	22 Normal	Absent	Absent	Absent	Absent	
198	Imipramine	Female	Evaluated	01/02/92	13/03/92	42	Day 42	14/03/92	43 Normal	Absent	Absent	Absent		
							Screen	01/02/92	1 Normal	Absent	Absent	Absent	Absent	

9550082

1987

(*) days of treatment

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific gravity	Albumin	Sugar	RBC
7/04	199	Imipramine	Male	Evaluated	28/03/92	08/05/92	42	Screen Day 21 Day 42	28/03/92	1 Normal	Absent	Absent	Absent
									18/04/92	22 Normal	Absent	Absent	Absent
									09/05/92	43 Normal	Absent	Absent	Absent
200	200	Placebo	Male	Evaluated	28/03/92	08/05/92	42	Screen Day 21 Day 42	28/03/92	1 Normal	Absent	Absent	Absent
									18/04/92	22 Normal	Absent	Absent	Absent
									09/05/92	43 Normal	Absent	Absent	Absent
201	201	Reboxetine	Female	Evaluated	28/03/92	08/05/92	42	Screen Day 21 Day 42	28/03/92	1 Not done	Absent	Absent	Absent
									18/04/92	22 Normal	Absent	Absent	Absent
									09/05/92	43 Normal	Absent	Absent	Absent
L1 C3 O8 O8	202	Reboxetine	Male	Evaluated	04/04/92	15/05/92	42	Screen Day 21 Day 42	01/04/92	0 Normal	Absent	Absent	Absent
									25/04/92	22 Normal	Absent	Absent	Absent
									16/05/92	43 Normal	Absent	Absent	Absent
203	203	Placebo	Female	Evaluated	04/04/92	15/05/92	42	Screen Day 21 Day 42	01/04/92	0 Normal	Absent	Absent	Absent
									25/04/92	22 Normal	Absent	Absent	Absent
									16/05/92	43 Normal	Absent	Absent	Absent
7/05	204	Imipramine	Female	Evaluated	04/04/92	15/05/92	42	Screen Day 21 Day 42	01/04/92	0 Normal	Absent	Absent	Absent
									25/04/92	22 Normal	Absent	Absent	Absent
									16/05/92	43 Normal	Absent	Absent	Absent
205	205	Placebo	Male	Evaluated	27/01/92	08/03/92	42	Screen Day 21 Day 42	01/04/92	0 Normal	Absent	Absent	Absent
									25/04/92	22 Normal	Absent	Absent	Absent
									16/05/92	43 Normal	Absent	Absent	Absent
206	206	Imipramine	Female	Evaluated	28/01/92	09/03/92	42	Screen Day 21 Day 42	30/12/91	0 Normal	Absent	Absent	Absent
									17/02/92	22 Normal	Absent	Absent	Absent
									09/03/92	43 Normal	Absent	Absent	Absent
207	207	Imipramine	Female	Evaluated	28/01/92	09/03/92	42	Screen Day 21 Day 42	16/01/92	0 Normal	Absent	Absent	Absent
									18/02/92	22 Normal	Absent	Absent	Absent
									10/03/92	43 Normal	Absent	Absent	Absent
208	208	Reboxetine	Male	Evaluated	30/01/92	11/03/92	42	Screen Day 21 Day 42	24/01/92	0 Normal	Absent	Absent	Absent
									20/02/92	22 Normal	Absent	Absent	Absent
									12/03/92	43 Normal	Absent	Absent	Absent

(*) days of treatment

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0
 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test												
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC					
7/05	209	Placebo	Male	Evaluated	05/02/92	17/03/92	42	Screen	29/01/92	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
									Day 21	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
	210	Reboxetine	Male	Evaluated	07/02/92	19/03/92	42	Screen	26/02/92	22 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
									Day 42	43 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
	541	Reboxetine	Female	Evaluated	17/03/92	27/04/92	42	Screen	03/02/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
									Day 21	22 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
	542	Imipramine	Male	Evaluated	17/03/92	27/04/92	42	Screen	02/03/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
									Day 21	22 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
	543	Imipramine	Male	Evaluated	18/03/92	28/04/92	42	Screen	07/04/92	43 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
									Day 42	43 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
544	Placebo	Female	Evaluated	24/03/92	04/05/92	42	Screen	02/03/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
								Day 21	22 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
545	Placebo	Male	Evaluated	25/03/92	05/05/92	42	Screen	07/04/92	43 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
								Day 42	43 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
546	Reboxetine	Female	Evaluated	25/03/92	05/05/92	42	Screen	09/03/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
								Day 21	22 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
7/07	529	Placebo	Female	Evaluated	18/02/92	30/03/92	42	Screen	15/04/92	43 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
									Day 42	43 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
530	Imipramine	Female	Only screening	20/02/92	09/03/92	19	Screen	17/02/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
								Day 21	22 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	

(*) days of treatment

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0
 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific gravity	Albumin	Sugar	RBC
7/07	531	Reboxetine	Female	Evaluated	24/02/92	05/04/92	42	Screen	18/02/92	0 Normal	Absent	Absent	Absent
								Day 21	17/03/92	23 Not done	Absent	Absent	Absent
								Day 42	06/04/92	43 Not done	Absent	Absent	Absent
532	Imipramine	Female	Evaluated	27/04/92	07/06/92	42	Screen	23/04/92	0 Not done	Absent	Absent	Absent	
							Day 21	18/05/92	22 Normal	Present	Absent	Absent	
							Day 42	09/06/92	44 Normal	Absent	Absent	Absent	
533	Reboxetine	Male	Without screen	04/05/92	14/06/92	42	Screen	27/04/92	0 Not done	Not done	Not done	Not done	
							Day 21	25/05/92	22 Normal	Absent	Absent	Absent	
							Day 42	15/06/92	43 Normal	Absent	Absent	Absent	
534	Placebo	Female	Evaluated	15/05/92	25/06/92	42	Screen	12/05/92	0 Normal	Absent	Absent	Present	
							Day 21	05/06/92	22 Normal	Absent	Absent	Present	
							Day 42	24/06/92	41 Normal	Absent	Absent	Absent	
8	211	Reboxetine	Female	Only screening	13/05/91	26/05/91	14	Screen	07/05/91	0 Normal	Absent	Absent	Absent
								Screen	10/09/91	0 Normal	Absent	Absent	Absent
								Screen	18/11/91	0 Normal	Absent	Absent	Absent
212	Placebo	Female	Only screening	14/09/91	25/10/91	42	Screen	10/09/91	0 Normal	Absent	Absent	Absent	
							Screen	19/11/91	0 Normal	Absent	Absent	Absent	
							Screen	13/12/91	21 Normal	Absent	Absent	Absent	
213	Imipramine	Male	Only screening	22/11/91	24/11/91	3	Screen	18/11/91	0 Normal	Absent	Absent	Absent	
							Screen	31/03/92	43 Normal	Absent	Absent	Absent	
							Screen	27/03/92	1 Normal	Absent	Absent	Absent	
214	Reboxetine	Female	Evaluated	23/11/91	03/01/92	42	Screen	19/11/91	0 Normal	Absent	Absent	Absent	
							Day 21	13/12/91	21 Normal	Absent	Absent	Absent	
							Day 42	05/05/92	40 Normal	Absent	Absent	Absent	
215	Placebo	Female	Without screen	18/02/92	30/03/92	42	Day 42	31/03/92	43 Normal	Absent	Absent	Absent	
							Screen	27/03/92	1 Normal	Absent	Absent	Absent	
							Day 21	14/04/92	19 Normal	Absent	Absent	Absent	
216	Imipramine	Male	Evaluated	27/03/92	07/05/92	42	Screen	27/03/92	1 Normal	Absent	Absent	Absent	
							Day 21	14/04/92	19 Normal	Absent	Absent	Absent	
							Day 42	05/05/92	40 Normal	Absent	Absent	Absent	
217	Reboxetine	Female	Evaluated	30/03/92	10/05/92	42	Screen	23/03/92	0 Normal	Absent	Absent	Absent	
							Day 21	20/04/92	22 Normal	Absent	Absent	Absent	
							Day 42	21/05/92	43 Normal	Absent	Absent	Absent	
218	Reboxetine	Female	Without screen	09/04/92	20/05/92	42	Day 42	21/05/92	43 Normal	Absent	Absent	Absent	
							Screen	09/04/92	43 Normal	Absent	Absent	Absent	
							Screen	21/05/92	43 Normal	Absent	Absent	Absent	

(*): days of treatment

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0
URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test					
										Specific gravity	Albumin	Sugar	WBC		
8	219	Placebo	Female	Only screening	11/04/92	01/05/92	21	Screen	08/04/92	0	Normal	Absent	Absent	Absent	Absent
	220	Imipramine	Female	Without screen	27/04/92	07/06/92	42	Day 21	18/05/92	22	Normal	Absent	Absent	Absent	Absent
	221	Imipramine	Male	Evaluated	28/04/92	08/06/92	42	Screen Day 21 Day 42	24/04/92 19/05/92 09/06/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	222	Placebo	Female	Evaluated	28/04/92	08/06/92	42	Screen Day 21 Day 42	20/04/92 19/05/92 28/06/92	0 22 62	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
1 9 1	223	Imipramine	Female	Without screen	11/05/92	21/06/92	42	Day 21	01/06/92	22	Normal	Absent	Absent	Absent	Absent
	224	Placebo	Female	Evaluated	07/09/92	18/10/92	42	Screen Day 21 Day 42	27/08/92 28/09/92 19/10/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	225	Placebo	Male	Evaluated	11/09/92	22/10/92	42	Screen Day 21 Day 42	05/09/92 02/10/92 23/10/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	226	Reboxetine	Male	Evaluated	23/09/92	03/11/92	42	Screen Day 21 Day 42	15/09/92 14/10/92 04/11/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	227	Reboxetine	Male	Evaluated	25/09/92	05/11/92	42	Screen Day 21 Day 42	18/09/92 15/10/92 06/11/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	228	Imipramine	Male	Only screening	26/09/92	02/10/92	7	Screen	19/09/92	0	Normal	Absent	Absent	Absent	Absent
	229	Imipramine	Female	Evaluated	30/09/92	10/11/92	42	Screen Day 21 Day 42	24/09/92 21/10/92 11/11/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent

(*) days of treatment

9550082

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test								
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	MBC	
8	230	Reboxetine	Female	Daily screening	28/09/92	08/11/92	42	Screen	24/09/92	0	Normal	Absent	Absent	Absent	Absent	Absent
	231	Imipramine	Male	Evaluated	30/09/92	10/11/92	42	Screen Day 21 Day 42	25/09/92 21/10/92 11/11/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	232	Reboxetine	Male	Evaluated	02/10/92	12/11/92	42	Screen Day 21 Day 42	25/09/92 23/10/92 13/11/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
11	233	Placebo	Female	Evaluated	07/10/92	17/11/92	42	Screen Day 21 Day 42	28/09/92 28/10/92 18/11/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
12	234	Placebo	Female	Evaluated	07/10/92	17/11/92	42	Screen Day 21 Day 42	30/09/92 28/10/92 18/11/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
8/A	235	Placebo	Female	Evaluated	14/10/92	24/11/92	42	Screen Day 21 Day 42	18/09/92 03/11/92 24/11/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	236	Placebo	Female	Evaluated	14/10/92	24/11/92	42	Screen Day 21 Day 42	18/09/92 03/11/92 24/11/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	237	Reboxetine	Female	Evaluated	14/10/92	24/11/92	42	Screen Day 21 Day 42	18/09/92 03/11/92 24/11/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	238	Reboxetine	Female	Evaluated	14/10/92	24/11/92	42	Screen Day 21 Day 42	18/09/92 03/11/92 24/11/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	239	Imipramine	Female	Evaluated	16/10/92	26/11/92	42	Screen Day 21 Day 42	22/09/92 05/11/92 26/11/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	

(*) days of treatment

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

26

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test					
										Specific gravity	Albumin	Sugar	RBC	MBC	
8/A	240	Imipramine	Female	Evaluated	16/10/92	26/11/92	42	Screen	22/09/92	0 Normal	Absent	Absent	Absent	Absent	Present
								Day 21	05/11/92	21 Normal	Absent	Absent	Absent	Present	
								Day 42	26/11/92	42 Normal	Absent	Absent	Absent	Present	
553	553	Placebo	Female	Evaluated	16/10/92	26/11/92	42	Screen	23/09/92	0 Normal	Absent	Absent	Absent	Present	
								Day 21	05/11/92	21 Normal	Absent	Absent	Absent	Present	
								Day 42	26/11/92	42 Normal	Absent	Absent	Absent	Present	
554	554	Reboxetine	Male	Evaluated	16/10/92	26/11/92	42	Screen	22/09/92	0 Normal	Absent	Absent	Absent	Present	
								Day 21	05/11/92	21 Normal	Absent	Absent	Absent	Present	
								Day 42	26/11/92	42 Normal	Absent	Absent	Absent	Present	
555	555	Reboxetine	Female	Evaluated	16/10/92	26/11/92	42	Screen	22/09/92	0 Normal	Absent	Absent	Absent	Present	
								Day 21	05/11/92	21 Normal	Absent	Absent	Absent	Present	
								Day 42	26/11/92	42 Normal	Absent	Absent	Absent	Present	
556	556	Imipramine	Male	Evaluated	16/10/92	26/11/92	42	Screen	22/09/92	0 Normal	Absent	Absent	Absent	Present	
								Day 21	05/11/92	21 Normal	Absent	Absent	Absent	Present	
								Day 42	26/11/92	42 Normal	Absent	Absent	Absent	Present	
9	241	Placebo	Female	Only screening	07/02/91	17/02/91	11	Screen	04/02/91	0 Normal	Absent	Absent	Absent	Present	
								Screen	12/02/91	0 Normal	Absent	Absent	Absent	Present	
								Day 21	11/03/91	22 Normal	Absent	Absent	Absent	Present	
242	242	Reboxetine	Female	Evaluated	18/02/91	11/03/91	22	Screen	12/02/91	0 Normal	Absent	Absent	Absent	Present	
								Day 21	11/03/91	22 Normal	Absent	Absent	Absent	Present	
								Screen	15/02/91	0 Normal	Absent	Absent	Absent	Present	
243	243	Reboxetine	Female	Evaluated	20/02/91	06/03/91	15	Day 14	06/03/91	15 Normal	Present	Absent	Present		
								Screen	16/02/91	0 Normal	Absent	Absent	Absent	Present	
								Day 21	12/03/91	22 Normal	Absent	Absent	Absent	Present	
244	244	Imipramine	Female	Evaluated	19/02/91	13/03/91	23	Screen	16/02/91	0 Normal	Absent	Absent	Absent	Present	
								Day 21	12/03/91	22 Normal	Absent	Absent	Absent	Present	
								Screen	18/02/91	0 Normal	Absent	Absent	Absent	Present	
245	245	Imipramine	Female	Evaluated	22/02/91	04/04/91	42	Day 21	15/03/91	22 Normal	Absent	Absent	Absent	Present	
								Day 42	05/04/91	43 Normal	Present	Absent	Absent	Present	
								Screen	13/02/91	0 Normal	Absent	Absent	Absent	Present	
246	246	Placebo	Female	Evaluated	22/02/91	17/03/91	24	Screen	13/02/91	0 Normal	Absent	Absent	Absent	Present	

(*) days of treatment

9550082

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27

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test				
										Specific gravity	Albumin	Sugar	RBC	
9	246	Placebo	Female	Evaluated	22/02/91	17/03/91	24	Day 21	15/03/91	22 Normal	Absent	Absent	Absent	Present
	247	Placebo	Female	Evaluated	25/02/91	26/03/91	30	Screen Day 21	20/02/91 18/03/91	0 Normal 22 Normal	Present Absent	Absent Absent	Absent Absent	Present Absent
	248	Placebo	Male	Evaluated	07/03/91	21/03/91	15	Screen Day 14	04/03/91 22/03/91	0 Normal 16 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	249	Reboxetine	Female	Only screening	08/03/91	11/03/91	4	Screen	04/03/91	0 Normal	Absent	Absent	Absent	Present
	250	Imipramine	Female	Evaluated	12/03/91	08/04/91	28	Screen Day 21 Day 28	07/03/91 02/04/91 08/04/91	0 Normal 22 Normal 28 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	251	Imipramine	Female	Evaluated	20/03/91	12/04/91	24	Screen Day 21	18/03/91 10/04/91	0 Normal 22 Normal	Absent Absent	Absent Absent	Absent Absent	Present Present
	252	Reboxetine	Female	Evaluated	02/04/91	20/04/91	19	Screen Day 21	28/03/91 20/04/91	0 Normal 19 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Present
	253	Reboxetine	Female	Only screening	02/04/91	08/04/91	7	Screen	29/03/91	0 Normal	Absent	Absent	Present	Absent
	254	Imipramine	Female	Evaluated	09/04/91	16/04/91	8	Screen Day 14	05/04/91 08/05/91	0 Normal 30 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Present
	255	Reboxetine	Female	Without screen	13/05/91	06/06/91	25	Screen Day 21	08/05/91 03/06/91	0 Not done 22 Normal	Not done Absent	Not done Absent	Not done Absent	Not done Present
	256	Imipramine	Female	Only screening	27/05/91	08/07/91	43	Screen Day 42	23/05/91 02/07/91	0 Normal 37 Not done	Absent Not done	Absent Not done	Absent Not done	Present Not done
	257	Placebo	Male	Only screening	25/06/91	01/07/91	7	Screen	21/06/91	0 Normal	Absent	Absent	Absent	Absent
	258	Placebo	Male	Only screening	01/07/91	10/07/91	10	Screen	26/06/91	0 Normal	Absent	Absent	Absent	Absent

(*) days of treatment

9550082

1994

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0
 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test									
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	NBC		
11	319	Placebo	Male	Without Urinal	02/08/91	12/09/91	42	Screen	25/07/91	0	Normal	Absent	Absent	Absent	Absent	Not done	
								Day 21	22/08/91	21	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	12/09/91	42	Not done	Absent	Absent	Absent	Absent	Not done	
320	320	Imipramine	Male	Without Urinal	17/08/91	26/09/91	41	Screen	06/08/91	0	Not done	Absent	Absent	Absent	Not done		
								Day 21	05/09/91	20	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	26/09/91	41	Not done	Absent	Absent	Absent	Absent	Not done	
321	321	Placebo	Male	Without Urinal	06/09/91	17/10/91	42	Screen	22/08/91	0	Not done	Present	Absent	Absent	Not done		
								Day 21	26/09/91	21	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	17/10/91	42	Not done	Absent	Absent	Absent	Absent	Not done	
322	322	Reboxetine	Female	Without Urinal	27/09/91	07/11/91	42	Screen	19/09/91	0	Not done	Absent	Absent	Absent	Not done		
								Day 21	17/10/91	24	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	07/11/91	42	Not done	Absent	Absent	Absent	Absent	Not done	
323	323	Reboxetine	Male	Without Urinal	15/11/91	26/12/91	42	Screen	05/11/91	0	Not done	Absent	Absent	Absent	Not done		
								Day 21	05/12/91	21	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	27/12/91	43	Not done	Absent	Absent	Absent	Absent	Not done	
324	324	Imipramine	Male	Without Urinal	06/12/91	16/01/92	42	Screen	20/11/91	0	Not done	Absent	Absent	Absent	Not done		
								Day 21	27/12/91	22	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	16/01/92	42	Not done	Absent	Absent	Absent	Absent	Not done	
325	325	Reboxetine	Male	Without Urinal	13/12/91	23/01/92	42	Screen	06/12/91	0	Not done	Absent	Absent	Absent	Not done		
								Day 21	02/01/92	21	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	23/01/92	42	Not done	Absent	Absent	Absent	Absent	Not done	
326	326	Placebo	Male	Without Urinal	16/01/92	27/02/92	43	Screen	14/01/92	0	Not done	Absent	Absent	Absent	Not done		
								Day 21	06/02/92	22	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	27/02/92	43	Not done	Absent	Absent	Absent	Absent	Not done	
327	327	Imipramine	Male	Without Urinal	30/01/92	05/02/92	7	Screen	23/01/92	0	Not done	Absent	Absent	Absent	Not done		
								Day 21	28/01/92	0	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	28/01/92	0	Not done	Absent	Absent	Absent	Absent	Not done	
328	328	Imipramine	Female	Without Urinal	31/01/92	04/02/92	5	Screen	01/04/92	0	Not done	Absent	Absent	Absent	Not done		
								Day 21	30/04/92	21	Not done	Absent	Absent	Absent	Absent	Not done	
								Day 42	30/04/92	21	Not done	Absent	Absent	Absent	Absent	Not done	

(*) days of treatment

9550082

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29

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0
URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test							
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
11	329	Placebo	Female	Without Urinal	10/04/92	21/05/92	42	Day 42	21/05/92	42	Not done	Absent	Absent	Absent	Not done
	330	Reboxetine	Male	Without Urinal	09/04/92	21/05/92	43	Screen Day 21 Day 42	06/04/92 30/04/92 21/05/92	0 22 43	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done	
	331	Imipramine	Male	Without Urinal	17/04/92	28/05/92	42	Screen Day 21 Day 42	08/04/92 07/05/92 28/05/92	0 21 42	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done	
	332	Reboxetine	Male	Without Urinal	19/05/92	29/06/92	42	Screen Day 21 Day 42	13/05/92 08/06/92 29/06/92	0 21 42	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done	
	333	Placebo	Male	Without Urinal	27/05/92	07/07/92	42	Screen Day 21 Day 42	18/05/92 16/06/92 07/07/92	0 21 42	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done	
	334	Reboxetine	Female	Without Urinal	29/05/92	31/05/92	3	Screen	21/05/92	0	Not done	Absent	Absent	Not done	
	335	Placebo	Male	Without Urinal	03/06/92	14/07/92	42	Screen Day 21 Day 42	21/05/92 23/06/92 14/07/92	0 21 42	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done	
	336	Imipramine	Female	Without Urinal	18/06/92	25/06/92	8	Screen	15/06/92	0	Not done	Absent	Absent	Not done	
	337	Reboxetine	Female	Without Urinal	02/07/92	13/08/92	43	Screen Day 21 Day 42	14/06/92 23/07/92 13/08/92	0 22 43	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done	
	338	Imipramine	Male	Without Urinal	23/07/92	30/07/92	8	Screen	14/07/92	0	Not done	Absent	Absent	Not done	
12	367	Reboxetine	Female	Evaluated	20/12/91	30/01/92	42	Screen Day 21 Day 42	18/12/91 10/01/92 31/01/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	368	Placebo	Female	Evaluated	24/12/91	03/02/92	42	Screen	19/12/91	0	Normal	Absent	Absent	Present	

1996

9550082

(*) days of treatment

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30

PHARMACIA CNS 88D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test						
										Specific Gravity	Albumin	Sugar	RBC	MBC	WBC	Leucocytes
12	368	Placebo	Female	Evaluated	24/12/91	03/02/92	42	Day 21 Day 42	14/01/92 04/02/92	22 Normal 43 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Present Present	Present Present
	369	Imipramine	Female	Evaluated	23/04/92	13/05/92	21	Screen Day 21	22/04/92 13/05/92	0 Normal 21 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Present Present	Present Present
	370	Placebo	Male	Evaluated	29/04/92	20/05/92	22	Screen Day 21	27/04/92 19/05/92	0 Normal 21 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Present Present	Present Present
	371	Imipramine	Female	Evaluated	01/05/92	06/05/92	6	Screen Day 7	21/04/92 08/05/92	0 Normal 8 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Present Present	Present Present
	372	Reboxetine	Male	Evaluated	02/06/92	13/07/92	42	Screen Day 21 Day 42	01/06/92 01/07/92 17/07/92	0 Normal 30 Normal 46 Normal	Absent Present Present	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	373	Reboxetine	Male	Evaluated	05/06/92	14/07/92	40	Screen Day 21 Day 42	05/06/92 25/06/92 14/07/92	1 Normal 21 Normal 40 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	374	Placebo	Female	Evaluated	09/06/92	05/07/92	27	Screen Day 21 Day 28	09/06/92 30/06/92 06/07/92	1 Normal 22 Normal 28 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	375	Imipramine	Male	Only screening	17/06/92	18/06/92	2	Screen	12/06/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent
13	13	Placebo	Male	Without Urinal	13/04/91	24/05/91	42	Screen Day 21 Day 42	04/04/91 02/05/91 24/05/91	0 Normal 20 Normal 42 Normal	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
	14	Placebo	Male	Evaluated	02/07/91	13/08/91	43	Screen Day 21 Day 42	09/07/91 24/07/91 15/08/91	8 Normal 23 Normal 45 Normal	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent
	15	Imipramine	Female	Without screen	05/07/91	15/08/91	42	Screen Day 21 Day 42	01/07/91 25/07/91 15/08/91	0 Normal 21 Normal 42 Normal	Not done Not done Absent	Not done Not done Absent	Not done Not done Absent	Not done Not done Absent	Not done Not done Absent	Not done Not done Absent

9550082

1997

(*) days of treatment

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31

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test											
					Start date	End date	Days	Assessment	Date	Specific Gravity	Alb	U	Sugar	RBC	MBC				
13	16	Imipramine	Male	Evaluated	03/12/91	16/01/92	45	Screen Day 28 Day 42	03/12/91	1 Normal	Absent	Absent	Absent	Absent	Absent	Absent			
										35 Not done	Absent	Absent	Absent	Absent	Absent				
										49 Normal	Absent	Absent	Absent	Absent	Absent				
17	17	Reboxetine	Male	Without screen	21/05/92	01/07/92	42	Screen Day 21 Day 42	23/05/92	3 Not done	Not done	Not done	Not done	Not done	Not done				
										22 Normal	Present	Absent	Present	Present					
										43 Normal	Absent	Absent	Absent	Absent					
18	18	Reboxetine	Male	Evaluated	24/06/92	02/08/92	40	Screen Day 21 Day 42	26/06/92	3 Normal	Absent	Absent	Absent	Present	Present				
										20 Normal	Present	Absent	Absent	Absent					
										41 Normal	Absent	Absent	Absent	Absent					
409	409	Reboxetine	Male	Evaluated	10/12/91	20/01/92	42	Screen Day 21 Day 42	10/12/91	1 Normal	Absent	Absent	Absent	Absent	Absent				
										25 Normal	Absent	Absent	Absent	Absent					
										44 Normal	Present	Absent	Absent	Absent					
410	410	Placebo	Male	Without Urinal	14/02/92	26/03/92	42	Screen Day 21 Day 42	11/02/92	0 Normal	Absent	Absent	Absent	Not done	Not done				
										22 Normal	Absent	Absent	Absent	Not done					
										43 Normal	Absent	Absent	Absent	Not done					
411	411	Imipramine	Female	Without Urinal	28/03/92	08/05/92	42	Screen Day 21 Day 42	20/03/92	0 Not done	Not done	Not done	Not done	Not done	Not done				
										20 Not done	Not done	Not done	Not done	Not done					
										39 Not done	Not done	Not done	Not done	Not done					
423	423	Placebo	Male	Evaluated	14/09/92	27/10/92	44	Screen Day 21 Day 42	14/09/92	1 Normal	Absent	Absent	Absent	Absent	Absent				
										22 Normal	Absent	Absent	Absent	Absent					
										46 Normal	Not done	Not done	Not done	Not done					
14	19	Reboxetine	Female	Evaluated	10/04/92	06/05/92	27	Screen Day 21 Day 28	03/06/92	0 Normal	Absent	Absent	Absent	Absent	Absent				
										22 Normal	Absent	Absent	Absent	Absent					
										28 Normal	Present	Absent	Present	Present					
20	20	Imipramine	Female	Evaluated	29/04/92	09/06/92	42	Screen Day 21 Day 42	27/04/92	0 Normal	Absent	Absent	Absent	Absent	Absent				
										22 Normal	Absent	Absent	Absent	Absent					
										52 Normal	Absent	Absent	Absent	Absent					
21	21	Imipramine	Female	Evaluated	20/07/92	24/08/92	36	Screen	16/07/92	0 Normal	Present	Absent	Present	Present	Present				
															(*) days of treatment				

9550082

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0
URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific gravity	Albunin	Sugar	RBC
14	21	Imipramine	Female	Evaluated	20/07/92	24/08/92	36	Day 21 Day 35	10/08/92 24/08/92	22 Normal 36 Normal	Absent Present	Absent Present	Absent Present
15	25	Reboxetine	Female	Evaluated	18/06/91	29/07/91	42	Screen Day 21 Day 42	17/06/91 09/07/91 30/07/91	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Present Absent	Absent Absent Absent
26	26	Placebo	Male	Evaluated	20/06/91	01/08/91	43	Screen Day 21 Day 42	17/06/91 10/07/91 01/08/91	0 Normal 21 Normal 43 Normal	Absent Absent Absent	Absent Present Absent	Absent Present Absent
27	27	Imipramine	Female	Evaluated	02/07/91	13/08/91	43	Screen Day 21 Day 42	27/06/91 23/07/91 13/08/91	0 Normal 22 Normal 45 Normal	Absent Absent Absent	Absent Present Present	Absent Absent Absent
28	28	Reboxetine	Female	Evaluated	08/08/91	19/09/91	43	Screen Day 21 Day 42	06/08/91 29/08/91 20/09/91	0 Normal 22 Normal 44 Normal	Absent Absent Absent	Absent Present Present	Absent Absent Absent
29	29	Placebo	Male	Without screen	29/08/91	19/09/91	22	Screen Day 21	29/08/91 19/09/91	1 Normal 22 Normal	Absent Absent	Absent Present	Not done Absent
30	30	Imipramine	Female	Evaluated	03/09/91	15/10/91	43	Screen Day 21 Day 42	03/09/91 24/09/91 15/10/91	1 Not done 22 Normal 43 Normal	Not done Absent Absent	Absent Present Absent	Absent Present Absent
403	403	Imipramine	Female	Evaluated	04/10/91	14/11/91	42	Screen Day 21 Day 42	04/10/91 28/10/91 14/11/91	1 Normal 25 Not done 42 Normal	Absent Absent Absent	Absent Present Absent	Present Absent Present
404	404	Reboxetine	Female	Evaluated	08/10/91	05/11/91	29	Screen Day 21	10/09/91 29/10/91	0 Normal 22 Normal	Absent Absent	Absent Present	Absent Absent
405	405	Placebo	Female	Evaluated	11/11/91	23/12/91	43	Screen Day 21 Day 42	11/11/91 02/12/91 23/12/91	1 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Present Absent	Absent Absent Absent
406	406	Imipramine	Male	Evaluated	27/11/91	07/01/92	42	Screen	27/11/91	1 Normal	Absent	Absent	Absent

9550082

(*): days of treatment

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33

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 19.0

URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific gravity	Albumin	Sugar	RBC
15	406	Imipramine	Male	Evaluated	27/11/91	07/01/92	42	Day 21 Day 42	17/12/91 07/01/92	21 Normal 42 Normal	Absent Absent	Absent Absent	Absent Absent
	407	Reboxetine	Female	Without screen	03/12/91	14/01/92	43	Screen Day 21 Day 42	02/12/91 24/12/91 14/01/92	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Not done Present Absent
	408	Placebo	Female	Evaluated	20/01/92	04/03/92	45	Screen Day 21 Day 42	09/01/92 10/02/92 04/03/92	0 Normal 22 Normal 45 Normal	Absent Absent Absent	Absent Not done Absent	Absent Not done Absent
	418	Placebo	Female	Evaluated	30/01/92	12/03/92	43	Screen Day 21 Day 42	30/01/92 20/02/92 12/03/92	1 Normal 22 Normal 45 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	419	Placebo	Female	Evaluated	28/04/92	09/06/92	43	Screen Day 21 Day 42	27/04/92 19/05/92 09/06/92	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent

2000

9550082

(*) days of treatment

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE								
									Lying			Standing					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)			
1	1	Imipramine	Female	Screen	10/04/91	36.70	15	54.00	115	80	94	110	82	94	94		
				Day 0	10/04/91	36.70		54.00	115	80	94	110	82	94	94	94	
				Day 7	17/04/91	37.10		52.00	122	86	86	116	82	82	110	82	82
				Day 14	24/04/91	37.00		52.00	122	82	82	115	82	82	115	82	82
				Day 21	01/05/91	36.70		53.50	110	70	85	104	68	68	104	68	88
2	2	Reboxetine	Male	Screen	11/04/91	36.80	16	76.00	145	90	81	140	88	88	89		
				Day 0	15/04/91	36.70		76.00	145	90	81	140	88	88	140	88	89
				Day 7	22/04/91	36.60		75.00	148	88	82	114	88	88	114	88	88
				Day 14	30/04/91	36.70		76.00	146	86	98	105	88	88	105	88	88
				Day 21	06/05/91	36.20		76.00	130	86	82	105	90	90	105	90	78
3	3	Imipramine	Male	Screen	02/05/91	36.30		77.50	112	92	79	120	80	80	68		
				Day 0	06/05/91	36.30		75.50	118	82	68	108	80	80	108	80	68
				Day 7	13/05/91	36.20		75.00	112	80	76	100	80	80	100	80	76
				Day 14	20/05/91	36.80		75.00	140	90	70	125	85	85	125	85	80
				Day 21	27/05/91	36.40		74.50	120	80	80	118	80	80	118	80	80
4	4	Placebo	Male	Screen	04/06/91	36.60		75.00	124	86	84	120	86	84	90		
				Day 0	04/06/91	36.60		75.00	128	92	60	116	86	86	116	86	90
				Day 7	11/06/91	36.40		93.00	130	80	88	120	88	88	120	88	84
				Day 14	18/06/91	36.50		93.00	130	88	90	126	88	88	126	88	92
				Day 21	25/06/91	36.50		93.00	125	80	80	125	80	80	125	80	80
5	5	Reboxetine	Female	Screen	12/06/91	37.08		67.00	118	84	62	118	86	86	60		
				Day 0	12/06/91	37.80		67.00	118	84	62	118	86	86	118	86	60
				Day 7	19/06/91	36.50		67.00	150	90	90	130	90	90	130	90	96
				Day 14	25/06/91	36.50		67.00	140	90	90	140	90	90	140	90	90
				Day 21	02/07/91	36.50		65.00	130	90	90	130	90	90	130	90	90
6	6	Placebo	Female	Screen	23/05/91	36.50		54.00	108	70	66	105	70	68			
				Day 0	23/05/91	36.50		54.00	108	70	66	105	70	66	105	70	68

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
1	6	Placebo	Female	Day 7	30/05/91	36.20		54.00	122	72	110	72	110	90
				Day 14	06/06/91	37.00		54.00	110	78	95	70	70	90
				Day 21	13/06/91	36.70		53.60	110	74	72	110	74	72
				Day 28	20/06/91	36.30		54.00	108	70	72	100	100	84
				Day 35	01/07/91	36.00		55.00	110	70	80	100	65	84
Day 42	08/07/91	37.00		54.00	120	60	84	130	70	92				
7	7	Reboxetine	Female	Screen	27/08/91	36.40			110	102	102	102	64	118
				Day 0	27/08/91	36.70		46.00	110	70	102	64	118	
				Day 7	03/09/91	36.40		48.00	104	60	105	70	40	140
				Day 14	10/09/91	36.50		48.00	98	60	96	70	50	110
				Day 21	17/09/91	36.40		48.00	104	66	84	88	58	120
Day 28	25/09/91	36.40		48.00	104	60	90	98	60	100				
Day 35	02/10/91	36.50		50.00	110	60	84	100	60	84				
Day 42	08/10/91	36.40		49.00	110	70	84	110	70	84				
8	8	Placebo	Male	Screen	05/09/91	36.40			122	84	72	122	84	72
				Day 0	05/09/91	36.40		64.00	122	84	122	84	84	
				Day 7	12/09/91	36.50		64.00	120	80	84	118	80	84
				Day 14	19/09/91	36.70		64.00	124	82	76	124	80	78
				Day 21	26/09/91	36.90		64.00	110	84	78	110	84	79
Day 28	03/10/91	36.90		64.00	105	70	72	100	70	76				
Day 35	10/10/91	36.90		68.00	110	75	70	108	74	70				
Day 42	17/10/91	36.90		68.00	110	75	70	108	74	70				
9	9	Reboxetine	Female	Day 0	27/11/91	36.90		64.00	95	74	90	74	70	80
				Day 7	04/12/91	37.20		63.50	105	72	96	77	77	82
				Day 14	11/12/91	36.90		65.00	98	60	62	94	60	65
				Day 21	18/12/91	36.80		65.00	102	80	70	100	80	66
				Day 28	25/12/91	37.20		66.00	112	70	70	106	70	66
Day 35	01/01/92	37.20		67.00	110	70	68	102	65	66				
Day 42	08/01/92	36.10		68.00	108	68	68	102	65	66				
10	10	Placebo	Male	Screen	24/09/91	36.80			116	70	72	116	70	74
				Day 0	24/09/91	36.80		77.00	116	70	72	116	70	74
				Day 7	01/10/91	36.40		77.00	110	85	75	110	85	78
				Day 14	08/10/91	36.70		77.00	118	70	74	118	70	76
				Day 21	15/10/91	36.70		77.00	120	70	80	120	70	85
Day 28	22/10/91	37.10		77.00	118	80	72	116	80	72				
Day 35	29/10/91	36.40		77.00	108	68	70	108	70	72				
Day 42	04/11/91	36.50		78.00	102	64	84	102	64	86				
11	11	Imipramine	Female	Screen	10/10/91	36.90		58.00	140	109	84	140	100	84
				Day 0	10/10/91	36.90		58.00	140	100	84	140	100	

2002

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0
VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE							
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing				
1	12	Imipramine	Female	Screen	18/10/91	37.10			116	78	78	108	76	84		
				Day 0	18/10/91	37.10		62.00	116	78	78	108	76	84		
				Day 7	25/10/91	37.10		63.00	118	80	76	105	80	88		
				Day 14	01/11/91	37.10		63.00	116	80	82	100	75	100		
				Day 21	08/11/91	36.50		63.00	105	80	86	95	80	97		
	Day 28	15/11/91	37.10		61.00	120	80	96	105	80	110					
	Day 35	22/11/91	37.40		66.00	112	74	73	102	75	80					
	Day 42	09/12/91	37.30		66.00	110	80	74	105	80	76					
	412	Reboxetine	Male	Screen	12/11/91	37.20			115	80	76	115	75	80		
				Day 0	12/11/91	37.20		76.00	115	80	76	115	75	80		
				Day 7	20/11/91	36.80		75.00	105	80	74	102	84	72		
				Day 14	27/11/91	36.90		75.00	112	84	96	106	84	100		
				Day 21	04/12/91	36.70		74.00	112	88	84	105	65	89		
	Day 28	11/12/91	36.80		74.00	118	90	84	115	80	72					
	Day 35	18/12/91	36.80		74.00	118	90	84	115	80	72					
Day 42	25/12/91	36.60		73.00	105	80	80	105	80	72						
413	Placebo	Male	Screen	03/12/91	37.00			120	75	84	116	75	84			
			Day 0	09/12/91	37.30		72.00	122	70	80	114	70	80			
			Day 7	16/12/91	36.70		71.00	122	68	74	120	70	76			
			Day 14	23/12/91	36.90		72.00	105	70	82	98	70	84			
			Day 21	30/12/91	37.00		72.50	112	72	82	112	70	70			
414	Imipramine	Female	Screen	21/01/92	37.00			120	90	104						
			Day 0	21/01/92	37.00		67.70	120	90	104						
			Day 7	28/01/92	37.00		65.00	110	75	80	105	75				
			Day 14	04/02/92	36.40		63.90	110	70	76						
			Day 21	11/02/92	37.10		65.00	110	70	76						
415	Imipramine	Male	Screen	14/01/92	37.10			142	84	96	130	82	105			
			Day 0	14/01/92	37.10		67.00	142	84	96	130	82	105			
			Day 7	21/01/92	37.10		66.00	145	88	92	136	90	101			
			Day 14	28/01/92	37.10		65.00	128	80	75	116	80	78			
			Day 21	04/02/92	36.80		65.00	140	90	68	110	84	71			
			Day 28	11/02/92	36.80		66.00	135	95	84	118	95	120			
			Day 35	18/02/92	37.10		66.00	130	85	75	122	100	78			
			Day 42	25/02/92	37.10		65.00	144	90	96	128	82	106			
			416	Reboxetine	Female	Screen	14/01/92	36.80			112	72	86	106	78	92
						Day 0	17/01/92	36.80		66.00	112	72	72	106	92	78
Day 7	24/01/92	36.20					61.00	108	76	79	105	75	84			
Day 14	30/01/92	36.30		61.00	125	80	82	120	76	84						

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2003

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 20.0
 VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	Standing Heart Rate (beats/min)			
1	421	Imipramine	Male	Screen	26/02/92	36.50				150	100	72	142	90	78
				Day 0	26/02/92	36.80		77.00	150	100	72	142	90	78	
				Day 7	05/03/92	36.70		76.00	112	86	96	108	80	100	
				Day 14	12/03/92	37.10		77.00	116	78	102	110	80	106	
				Day 21	19/03/92	36.40			112	76	87	110	78	92	
				Day 28	26/03/92	37.10		79.00	115	86	84	111	84	84	
				Day 35	02/04/92	37.10		79.00	142	88	96	124	84	103	
				Day 42	09/04/92	36.60		78.00	118	90	76	105	84	80	
				Screen	06/08/92	36.60			140	90	90	132	88	94	
				Day 0	06/08/92	36.60		61.00	140	90	90	132	88	94	
2/1	49	Placebo	Female	Day 7	12/08/92	36.70		62.00	135	88	88	118	88	92	
				Day 14	19/08/92	37.20		62.00	130	86	72	120	84	96	
				Day 21	26/08/92	36.90		64.00	135	105	96	122	95	104	
				Day 28	02/09/92	36.90		63.50	128	90	96	122	90	96	
				Day 42	17/09/92	37.10		61.00	135	90	78	130	90	80	
				Screen	14/05/91	36.80	24		180	60	72	95	60	100	
				Day 0	18/05/91	37.00		60.00	105	65	76	100	60	104	
				Day 7	25/05/91	36.80		59.00	110	70	96	120	80	104	
				Day 14	01/06/91	36.50		60.50	110	60	80	120	70	96	
				Day 21	08/06/91	36.60		60.50	95	50	66	105	60	81	
Day 28	14/06/91	35.90		60.50	100	70	78	110	75	88					
Day 35	22/06/91	37.10		61.50	105	70	72	110	80	80					
Day 42	29/06/91	36.80		62.00	100	70	70	110	70	76					
50	50	Reboxetine	Female	Screen	23/12/91	37.10	18		135	95	84	140	100	95	
				Day 0	26/12/91	37.10		50.00	150	95	88	140	100	94	
				Day 7	02/01/92	36.90		50.00	125	95	68	130	95	76	
				Day 14	09/01/92	36.90		50.00	140	100	80	130	95	88	
				Day 21	16/01/92	37.20		50.50	110	90	68	125	80	76	
				Day 28	23/01/92	37.30		51.00	120	85	72	125	95	76	
				Day 35	30/01/92	36.90		51.00	130	95	96	125	100	92	
				Day 42	06/02/92	37.30		51.00	125	80	92	125	80	88	
				Screen	28/01/92	36.40	18		110	70	72	95	70	76	
				Day 0	01/02/92	36.20		68.00	130	60	64	125	80	92	
Day 7	08/02/92	37.00		66.00	120	70	66	90	75	70					
Day 14	15/02/92	37.00		66.00	135	90	68	130	90	86					
Day 21	24/02/92	37.00		66.00	110	70	88	130	70	100					
Day 28	03/03/92	37.00		67.00	120	90	76	120	80	79					
Day 35	09/03/92	36.80		66.00	120	65	88	125	80	80					
Day 42	16/03/92	36.90		67.00	115	70	68	105	70	68					

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2004

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 2012A/015
 Listing No.: 20.0
 VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
2/2	43	Imipramine	Female	Screen	11/04/91	37.00	16		105	75	68	115	75	84
				Day 0	18/04/91	37.00		61.00	105	75	68	115	75	84
				Day 7	25/04/91	37.70		61.00	100	75	60	95	80	88
				Day 14	02/05/91	37.00		61.00	105	70	88	122	95	104
				Day 28	13/05/91	37.00		62.00	115	70	88	122	95	94
	44	Imipramine	Female	Screen	12/07/91	37.00	22		130	85	80	120	85	80
				Day 0	19/07/91	37.00		62.00	130	80	74	125	90	104
				Day 7	25/07/91	37.80		61.00	135	80	88	100	60	134
				Day 14	01/08/91	37.50		62.70	145	70	92	105	80	112
				Day 21	08/08/91	37.50		62.90	125	80	88	115	90	112
	45	Reboxetine	Female	Screen	27/08/91	37.30	15		110	85	64	120	90	100
				Day 0	07/09/91	37.30		60.20	110	70	68	105	75	84
				Day 7	15/09/91	37.40		61.60	110	80	52	100	70	76
				Day 14	22/09/91	37.40		60.50	110	80	54	80	60	80
				Day 21	30/09/91	37.10		60.50	110	95	64	85	85	96
	46	Placebo	Female	Screen	18/09/91	37.40		62.00	110	80	60	110	85	80
				Day 0	26/09/91	37.40		64.50	110	80	60	100	70	80
				Day 7	03/10/91	36.80		63.00	120	80	64	105	85	72
				Day 14	10/10/91	37.00		63.00	120	80	64	125	95	80
				Day 28	23/10/91	37.00		63.00	120	85	84	130	90	84
	47	Placebo	Female	Screen	13/03/92	37.00	16		105	65	84	100	65	94
				Day 0	24/03/92	37.00		53.00	130	90	64	125	85	70
				Day 7	31/03/92	37.00		54.00	110	80	110	110	80	80
				Day 14	07/04/92	37.00		53.00	125	85	66	115	80	67
				Day 21	14/04/92	37.00		53.00	120	80	70	120	65	67
	48	Reboxetine	Female	Screen	09/04/92	37.00	17		140	90	105	130	90	102
				Day 0	07/04/92	37.00		64.00	140	90	90	140	90	88

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2005

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PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Contra	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
2/2	48	Reboxetine	Female	Day 7	14/04/92	37.00		64.00	125	90	130	100	80	80
				Day 14	21/04/92	37.00		64.00	120	70	85	130	95	80
				Day 21	28/04/92	37.00		64.00	130	90	80	130	100	80
				Day 28	06/05/92	37.00		65.00	135	90	80	135	110	80
				Day 35	12/05/92	37.00		65.00	135	110	80	130	110	80
				Day 42	20/05/92	37.00		65.00	130	90	82	135	95	84
2/3	36/A	Imipramine	Male	Screen	06/03/91	37.10	15	99.00	130	80	88	130	80	88
				Day 0	06/03/91	37.20		99.00	130	70	80	130	70	80
				Day 7	13/03/91	37.40		99.00	135	80	80	120	80	86
				Day 14	20/03/91	37.40		99.00	130	80	80	120	80	86
				Day 21	28/03/91	37.00		99.00	130	80	80	120	80	80
				Day 28	03/04/91	37.10		98.00	130	80	80	130	80	80
				Day 35	10/04/91	37.50		99.00	140	80	80	140	80	80
				Day 42	17/04/91	37.00		99.00	130	70	80	140	80	80
2006	37	Reboxetine	Female	Screen	18/03/91	35.50	15	43.00	120	88	78	120	80	82
				Day 0	26/03/91	37.50		43.00	130	80	72	120	80	72
				Day 7	02/04/91	37.50		43.00	130	80	72	120	80	72
				Day 14	09/04/91	37.50		43.00	130	80	100	130	80	100
				Day 21	16/04/91	37.10		43.00	130	80	90	130	90	90
				Day 28	23/04/91	37.40		43.00	125	80	90	120	80	90
				Day 35	30/04/91	37.20		43.00	120	80	80	110	80	84
				Day 42	07/05/91	37.40		44.00	120	80	90	115	80	90
38		Placebo	Male	Screen	10/08/91	37.50	16	94.00	135	80	80	130	80	86
				Day 0	14/08/91	37.50		94.00	135	80	80	130	80	80
				Day 7	20/08/91	37.40		94.00	135	80	80	135	80	80
				Day 14	28/08/91	37.40		96.00	130	80	76	130	80	80
				Day 21	05/09/91	37.10		94.00	130	80	76	130	80	80
				Day 28	12/09/91	37.40		94.00	140	80	76	135	80	80
				Day 35	19/09/91	37.00		95.00	140	80	80	140	80	80
				Day 42	26/09/91	37.20		94.00	140	80	80	135	80	72
39		Imipramine	Female	Screen	05/08/91	37.00	15	58.00	130	85	85	130	85	80
				Day 0	09/08/91	37.50		60.00	130	80	100	125	80	100
				Day 7	16/08/91	37.40		60.00	125	80	90	130	80	100
				Day 14	23/08/91	37.40		60.00	120	70	80	120	70	90
				Day 21	30/08/91	37.20		60.00	125	85	95	105	75	98
				Day 28	06/09/91	37.30		58.00	130	80	90	130	80	90
				Day 35	13/09/91	37.30		58.00	125	85	80	130	85	80
				Day 42	20/09/91	37.00		60.00	140	80	88	130	80	90
40		Reboxetine	Female	Screen	24/10/91	37.00	16	110	110	60	90	100	60	90

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	Heart Rate (beats/min)	standing S.B.P. (mmHg)
2/3	40	Reboxetine	Female	Day 0	24/10/91	37.00		38.00	110	70	90	100	60	90
				Day 7	31/10/91	37.00		40.00	100	50	104	90	50	106
				Day 14	07/11/91	37.20		41.00	110	60	84	110	60	90
				Day 21	14/11/91	37.00		41.00	120	60	84	110	60	90
				Day 28	21/11/91	36.80		41.00	130	70	84	120	70	84
Day 35	28/11/91	36.80		41.50	110	60	78	110	60	84				
Day 42	05/12/91	37.20		42.00	130	70	68	120	70	72				
41	41	Placebo	Male	Screen	26/09/91	37.00	20		140	70	120	140	70	120
				Day 0	03/10/91	37.00		63.00	140	70	100	130	70	120
				Day 7	10/10/91	37.00		63.00	125	60	90	110	60	90
				Day 14	17/10/91	37.00		63.00	120	70	84	130	70	84
				Day 21	24/10/91	37.00		66.00	110	60	100	100	60	120
Day 28	31/10/91	36.50		65.00	105	60	90	100	60	104				
Day 35	06/11/91	37.10		65.00	110	70	84	110	70	90				
Day 42	14/11/91	37.20		65.50	120	60	72	130	60	84				
42	42	Imigranin	Female	Screen	06/05/92	37.00	15		130	70	92	120	80	92
				Day 0	18/05/92	37.00		78.00	130	90	90	120	80	90
				Day 7	25/05/92	37.30		78.00	130	80	84	120	80	90
				Day 14	01/06/92	37.00		78.00	140	70	90	120	60	96
				Day 21	09/06/92	37.00		78.00	130	80	96	120	70	96
Day 28	16/06/92	37.00		78.00	110	80	72	120	80	72				
Day 35	23/06/92	37.50		77.00	130	70	76	120	70	80				
Day 42	30/06/92	37.00		78.00	130	70	78	120	70	84				
2/4	31	Placebo	Male	Screen	18/03/91	36.50	20		130	70	80	130	70	80
				Day 0	25/03/91	36.50		75.00	125	70	78	130	70	80
				Day 7	01/04/91	36.40		75.00	130	70	80	130	70	80
				Day 14	08/04/91	37.00		75.00	125	70	80	130	70	80
				Day 21	15/04/91	37.00		75.00	125	70	80	130	70	80
Day 28	22/04/91	36.40		75.00	130	70	72	130	70	75				
Day 35	29/04/91	36.30		75.00	125	60	75	125	60	75				
Day 42	06/05/91	36.40		75.00	125	60	75	125	60	75				
32	32	Reboxetine	Male	Screen	18/10/91	36.70	30		130	70	60	130	70	64
				Day 0	25/10/91	36.80		80.00	120	70	62	120	70	65
				Day 7	01/11/91	36.70		80.00	130	70	62	130	70	65
				Day 14	08/11/91	36.80		80.00	130	70	60	130	70	64
				Day 21	15/11/91	36.80		80.00	110	70	75	110	70	80
Day 28	22/11/91	36.70		80.00	130	70	82	130	70	85				
Day 35	29/11/91	36.80		80.00	125	70	84	125	70	88				
Day 42	06/12/91	36.80		80.00	130	70	86	130	70	90				

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE									
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)				
2/4	33	Imipramine	Male	Screen	22/05/91	36.40	20	80.00	130	75	76	130	75	76				
				Day 0	23/05/91	36.40		80.00	130	70	76	130	70	75				
				Day 7	05/06/91	36.60		80.00	125	60	76	130	70	70				
				Day 14	12/06/91	36.50		80.00	130	70	76	130	70	70				
				Day 21	19/06/91	36.50		80.00	130	70	76	130	70	76				
				Day 28	26/06/91	36.40		80.00	135	79	78	135	75	79				
				Day 35	03/07/91	36.50		80.00	135	75	78	135	75	78				
				Day 42	10/07/91	36.50		80.00	135	75	78	135	75	78				
				2008	34	Placebo	Female	Screen	10/04/92	36.50	17	42.00	130	70	78	130	70	81
								Day 0	17/04/92	36.50		42.00	130	70	80	130	70	82
Day 7	24/04/92	36.50						42.00	130	70	78	130	70	80				
Day 14	01/05/92	36.40						42.00	125	70	78	125	70	80				
Day 21	08/05/92	36.50						42.00	130	70	76	130	70	78				
Day 28	15/05/92	36.60						42.00	125	70	76	125	70	77				
Day 35	22/05/92	36.40						42.00	130	70	80	130	70	80				
Day 42	29/05/92	36.60						42.00	120	70	75	120	70	77				
	35	Reboxetine	Female					Screen	08/09/92	36.60	30	65.00	130	60	76	130	60	78
								Day 0	15/09/92	36.50		65.00	130	60	74	130	60	76
				Day 7	22/09/92	36.40		65.00	125	60	76	125	60	78				
				Day 14	29/09/92	36.70		65.00	130	60	78	130	60	80				
				Day 21	06/10/92	36.60		65.00	135	70	75	135	70	80				
				Day 28	13/10/92	36.50		65.00	120	60	74	120	60	76				
				Day 35	20/10/92	36.70		65.00	125	65	76	130	70	78				
				Day 42	27/10/92	36.50		65.00	135	70	75	135	70	80				
					36	Imipramine	Female	Screen	05/02/92	36.60	24	45.00	130	70	60	130	70	62
								Day 0	12/02/92	36.50		45.00	130	70	72	130	70	75
Day 7	19/02/92	36.60						45.00	125	60	62	130	60	66				
Day 14	26/02/92	36.60						45.00	130	60	65	130	60	67				
Day 21	04/03/92	36.50						45.00	130	60	64	130	60	66				
Day 28	11/03/92	36.60						45.00	130	60	68	130	60	70				
Day 35	18/03/92	36.70						45.00	130	60	66	130	60	67				
Day 42	25/03/92	36.50						45.00	130	60	62	130	60	65				
2/5	73	Placebo	Male					Screen	03/02/92	37.00		73.00	120	70	80	120	70	80
								Day 0	06/02/92	37.00		73.00	120	80	80	120	80	80
				Day 7	14/02/92	37.00		72.00	110	50	72	115	70	72				
				Day 14	21/02/92	37.00		71.00	120	60	72	120	70	72				
				Day 21	28/02/92	37.00		72.00	120	80	80	110	80	78				
				Day 28	06/03/92	37.00		72.00	120	70	78	125	70	84				
				Day 35	13/03/92	37.00		71.00	110	60	72	120	70	76				
				Day 42	20/03/92	37.00		72.00	120	70	76	120	70	78				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing			
2/5	74	Reboxetine	Male	Screen	16/06/92	37.00			130	70	78	130	70	78	
				Day 0	20/06/92	36.50		65.00	125	70	80	125	70	80	80
				Day 7	27/06/92	37.00		65.00	130	70	76	130	70	76	76
				Day 14	04/07/92	36.00		65.00	135	70	78	135	70	78	78
				Day 21	11/07/92	37.00		64.00	110	70	100	110	70	120	100
				Day 28	18/07/92	36.50		64.00	105	70	100	105	70	100	100
				Day 35	25/07/92	37.00		64.00	110	75	98	110	75	110	110
				Day 42	01/08/92	37.00		64.00	115	70	78	110	70	78	110
				Screen	03/09/92	36.50			110	70	82	110	70	82	110
				Day 0	10/09/92	37.00		71.00	130	80	78	130	80	78	130
75		Imipramine	Male	Day 7	17/09/92	37.00		71.00	120	70	80	120	70	80	
				Day 14	24/09/92	37.00		71.00	130	70	76	130	70	76	76
				Day 21	01/10/92	37.00		72.00	130	70	78	130	70	78	78
				Day 28	08/10/92	37.00		72.00	130	70	80	130	70	80	80
				Day 35	15/10/92	37.00		71.00	120	70	88	120	70	88	120
				Day 42	22/10/92	37.00		71.00	130	70	80	125	70	80	125
				Screen	12/09/92	37.00			100	70	70	110	70	70	110
				Day 0	15/09/92	37.00		45.00	100	70	72	100	70	72	100
				Day 7	21/09/92	36.50		46.00	95	70	74	95	70	74	95
				Day 14	28/09/92	37.00		46.00	95	50	70	95	50	70	95
76		Imipramine	Female	Day 21	05/10/92	36.00		48.00	92	70	76	90	50	90	
				Day 28	12/10/92	37.00		48.00	92	70	76	90	50	90	
				Day 35	19/10/92	36.80		48.50	90	50	76	90	50	76	
				Day 42	26/10/92	37.00		49.00	90	60	80	90	60	80	
				Screen	15/09/92	37.00			140	70	76	140	70	76	140
				Day 0	21/09/92	37.00		77.00	135	70	76	130	70	76	130
				Day 7	28/09/92	37.00		77.00	130	70	76	130	70	76	130
				Day 14	05/10/92	37.00		77.00	130	70	76	130	70	76	130
				Day 21	12/10/92	37.00		76.50	120	70	78	120	70	78	120
				Day 28	19/10/92	37.00		77.00	115	70	80	120	70	80	120
Day 35	26/10/92	36.90		77.00	120	70	78	120	70	78	120				
Day 42	02/11/92	37.00		78.00	125	70	80	130	70	80	130				
77		Placebo	Male	Screen	15/09/92	37.00			140	70	76	140	70	76	
				Day 0	21/09/92	37.00		77.00	135	70	76	130	70	76	130
				Day 7	28/09/92	37.00		77.00	130	70	76	130	70	76	130
				Day 14	05/10/92	37.00		77.00	130	70	76	130	70	76	130
				Day 21	12/10/92	37.00		76.50	120	70	78	120	70	78	120
				Day 28	19/10/92	37.00		77.00	115	70	80	120	70	80	120
				Day 35	26/10/92	36.90		77.00	120	70	78	120	70	78	120
				Day 42	02/11/92	37.00		78.00	125	70	80	130	70	80	130
				Screen	01/10/92	37.00			105	70	76	105	70	76	105
				Day 0	09/10/92	37.00		57.00	105	70	72	105	70	72	105
78		Reboxetine	Female	Day 7	16/10/92	36.80		57.00	110	70	70	110	70	70	
				Day 14	23/10/92	37.00		57.00	120	70	74	120	70	74	120
				Day 21	30/10/92	36.80		58.00	125	60	70	125	60	70	125
				Day 28	06/11/92	37.00		58.00	115	70	76	120	70	76	120
				Day 35	13/11/92	37.00		58.00	130	70	80	130	70	80	130

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE								
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing					
2/6	55	Reboxetine	Female	Screen	12/06/92	37.00	17	55.00	140	80	76	130	80	74			
				Day 0	12/06/92	37.00			140	80	76	130	80	76			
				Day 7	19/06/92	37.00			140	80	78	130	80	76			
				Day 14	26/06/92	37.00			130	80	74	130	80	74			
				Day 21	03/07/92	37.00			130	80	74	120	80	74			
				Day 28	10/07/92	37.00			120	80	70	110	80	70			
				Day 35	17/07/92	37.00		55.00	120	80	74	120	80	74			
				Day 42	24/07/92	37.00		55.00	120	80	74	120	80	74			
				56	Reboxetine	Female	Screen	12/06/92	37.00	18	64.00	150	90	76	140	90	74
							Day 0	12/06/92	37.20		64.00	150	90	74	140	90	74
							Day 7	19/06/92	37.20		64.00	150	90	76	140	90	76
							Day 14	26/06/92	37.00		64.00	130	80	72	110	80	76
Day 21	03/07/92	37.00					64.00	130	80	76	120	80	76				
Day 28	10/07/92	37.00					64.00	130	80	74	120	80	74				
				Day 35	17/07/92	37.00		64.00	140	80	74	130	80	74			
				Day 42	24/07/92	37.00		64.00	140	80	76	130	80	76			
				57	Imipramine	Female	Screen	05/05/92	37.00	18	60.00	140	80	74	130	80	72
							Day 0	05/05/92	37.00		60.00	140	80	72	130	80	72
							Day 7	12/05/92	37.00		60.00	140	90	72	120	80	72
							Day 14	19/05/92	37.00		60.00	130	80	74	130	80	74
Day 21	26/05/92	37.00					60.00	130	80	76	120	70	76				
Day 28	02/06/92	37.00					60.00	130	80	76	120	80	76				
				Day 35	09/06/92	37.00		62.00	130	70	80	90	60	80			
				Day 42	16/06/92	37.00		63.00	100	70	80	90	70	80			
				58	Placebo	Female	Screen	18/05/92	37.00	20	55.00	130	80	74	120	80	74
							Day 0	18/05/92	37.00		55.00	130	80	76	120	80	76
							Day 7	25/05/92	37.00		55.00	140	90	80	120	90	80
							Day 14	01/06/92	37.00		56.00	130	80	76	120	80	76
Day 21	09/06/92	37.00					56.00	130	90	74	120	90	74				
Day 28	16/06/92	37.00					55.00	130	90	74	120	90	74				
				Day 35	23/06/92	37.00		55.00	120	80	74	110	80	76			
				Day 42	30/06/92	37.00		55.00	120	80	74	120	80	74			
				59	Placebo	Male	Screen	27/05/92	37.00	18	70.00	130	80	76	120	80	72
							Day 0	27/05/92	37.00		70.00	130	80	74	120	80	74
							Day 7	03/06/92	37.00		70.00	140	90	76	130	90	76
							Day 14	10/06/92	37.00		70.00	130	80	76	130	80	76
Day 21	17/06/92	37.00					70.00	120	70	76	120	80	76				
Day 28	24/06/92	37.00					70.00	130	80	76	120	70	76				

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PHARMACIA CNS RED

REBOMETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing			
2/6	60	Imipramine	Female	Screen	12/05/92	37.00	18	47.00	130	80	74	120	80	72	
				Day 0	12/05/92	37.20		47.00	130	80	76	120	80	76	
				Day 7	19/05/92	37.20		47.00	120	80	74	120	80	74	
				Day 14	26/05/92	37.20		49.00	110	70	76	90	60	76	
				Day 21	02/06/92	37.20		49.00	100	70	76	90	60	76	
3/1	61	Imipramine	Male	Screen	25/02/91	37.00		50.00	90	70	78	80	60	78	
				Day 0	04/03/91	37.00		50.00	90	70	75	80	60	76	
				Day 7	11/03/91	37.00		79.00	110	70	76	115	70	80	
				Day 14	18/03/91	37.00		79.00	115	70	76	110	70	84	
				Day 21	25/03/91	37.00		78.00	105	70	84	110	70	88	
62	62	Imipramine	Female	Screen	03/04/91	37.00		77.00	115	60	80	120	60	86	
				Day 28	03/04/91	37.00		77.00	130	80	78	130	80	80	
				Day 35	08/04/91	37.00		77.00	120	60	80	125	60	86	
				Screen	12/04/91	37.00		60.00	110	60	69	110	110	65	70
				Day 0	16/04/91	37.00		60.00	110	65	74	110	110	70	80
63	63	Placebo	Male	Screen	13/05/91	37.00		70.00	120	60	80	120	65	84	
				Day 0	13/05/91	37.00		70.00	120	60	84	120	65	82	
				Day 7	20/05/91	37.00		70.00	120	60	80	120	60	82	
				Day 14	27/05/91	37.00		70.00	120	60	80	120	70	82	
				Day 21	03/06/91	37.00		70.00	120	70	80	120	75	84	
64	64	Placebo	Female	Screen	08/03/91	37.00		63.00	100	60	88	105	60	90	
				Day 0	13/03/91	37.00		63.00	110	60	86	115	60	88	
				Day 7	20/03/91	37.00		63.00	130	80	80	140	80	80	
				Day 14	28/03/91	37.00		63.00	130	70	80	130	70	86	
				Day 21	03/04/91	37.00		63.00	130	90	80	130	90	84	
Day 28	10/04/91	37.00		63.00	130	80	78	130	80	80					
Day 35	17/04/91	37.00		63.00	125	80	80	130	80	84					
Day 42	24/04/91	37.00		63.00	120	80	80	130	80	80					

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2011

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12

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (KG)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
3/1	65	Reboxetine	Male	Screen	11/09/91	37.00			120	65	82	115	70	80
				Day 0	16/09/91	37.00		70.00	110	60	72	110	65	72
				Day 7	23/09/91	37.00		70.50	120	70	76	120	70	78
				Day 14	30/09/91	37.00		70.50	120	65	80	120	70	82
				Day 21	07/10/91	37.00		70.50	125	60	70	120	70	70
				Day 28	14/10/91	37.00		71.00	110	65	76	105	70	80
				Day 35	21/10/91	37.00		71.00	110	65	76	110	70	78
				Day 42	28/10/91	37.00		71.00	110	60	76	110	65	78
				Screen	05/06/91			140	70	76	130	60	82	
				Day 0	10/06/91			90.00	70	76	130	60	80	
66		Reboxetine	Male	Day 7	17/06/91			90.00	70	80	130	70	84	
				Day 14	24/06/91			90.00	70	92	130	70	100	
				Day 21	01/07/91			89.00	70	88	130	70	92	
				Day 28	08/07/91			88.50	140	90	140	90	90	
				Day 35	15/07/91			89.00	130	90	130	90	84	
				Day 42	22/07/91			89.00	160	100	140	80	98	
				Screen	28/08/91			130	80	96	120	80	100	
				Day 0	02/09/91			61.00	80	80	125	80	80	
				Day 7	09/09/91			61.00	80	92	130	80	100	
				Day 14	16/09/91			61.00	60	100	110	60	104	
140		Placebo	Male	Screen	04/09/91			67.00	110	72	105	60	70	
				Day 0	11/09/91			67.00	110	70	110	70	70	
				Day 7	18/09/91			67.00	130	80	120	80	68	
				Day 14	25/09/91			67.00	130	80	120	80	76	
				Day 21	03/10/91			67.00	120	60	72	120	60	
				Day 28	09/10/91			67.00	120	68	120	80	72	
				Day 35	15/10/91			67.50	125	80	125	80	76	
				Day 42	23/10/91			67.00	120	72	120	80	76	
				Screen	25/09/91			110	60	80	105	60	86	
				Day 0	02/10/91			56.50	100	84	95	60	88	
141		Placebo	Female	Day 7	09/10/91			57.00	110	86	100	60	88	
				Day 14	16/10/91			56.00	100	80	100	60	88	
				Day 21	23/10/91			56.00	110	80	110	60	88	
				Day 28	30/10/91			56.00	110	86	105	60	90	
				Day 35	06/11/91			55.00	115	70	110	70	88	
				Day 42	14/11/91			55.00	115	80	110	60	84	
				Screen	14/11/91			37.00	120	60	76	110	70	
				Day 0	21/11/91									
				Day 7	28/11/91									
				Day 14	05/12/91									

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2012

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13

PHARMACIA CNS 8&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing Heart Rate (beats/min)		
3/1	142	Imipramine	Female	Day 0	18/11/91	37.00		50.00	120	60	80	110	65	82
				Day 7	25/11/91	37.00	50.00	120	60	80	120	65	82	
				Day 14	02/12/91	37.00	50.00	110	60	87	120	70	88	
				Day 21	09/12/91	37.00		50.00	120	60	80	115	65	82
143	143	Reboxetine	Female	Screen	08/04/92				130	70	76	120	60	80
				Day 0	15/04/92	48.00		48.00	125	70	72	120	70	78
				Day 7	22/04/92	48.00		48.00	105	60	64	100	60	68
				Day 21	06/05/92	48.00		48.00	110	60	68	110	60	72
				Day 28	13/05/92	48.00		48.00	120	60	68	120	60	76
				Day 35	20/05/92	48.00		48.00	110	60	72	115	60	80
144	144	Reboxetine	Female	Screen	01/06/92			42.00	110	60	86	110	60	88
				Day 0	09/06/92			43.00	110	60	90	105	60	88
				Day 7	15/06/92			43.00	95	60	100	95	60	98
				Day 14	22/06/92			44.00	100	60	90	100	60	92
				Day 28	06/07/92			44.00	100	60	88	95	60	92
				Day 35	13/07/92			44.00	100	70	86	100	70	92
				Day 42	22/07/92			44.00	105	60	78	100	60	88
451	451	Reboxetine	Female	Screen	15/01/92			76.00	150	80	86	140	80	88
				Day 0	20/01/92			76.00	130	70	78	120	60	82
				Day 7	27/01/92			75.00	130	80	90	120	80	96
				Day 14	03/02/92			75.00	130	80	90	130	80	88
452	452	Placobo	Male	Screen	15/01/92			70.00	120	80	86	120	80	88
				Day 0	22/01/92			71.00	135	70	84	130	70	88
				Day 7	29/01/92			70.00	130	80	80	130	80	84
				Day 14	05/02/92			69.00	130	80	80	125	80	84
				Day 21	12/02/92			69.00	130	80	80	130	80	84
				Day 28	19/02/92			69.00	130	80	80	130	80	84
				Day 35	26/02/92			69.00	115	60	80	110	60	86
				Day 42	04/03/92			69.00	120	60	76	120	60	80
453	453	Imipramine	Female	Screen	22/01/92			72.00	140	70	80	140	70	84
				Day 0	29/01/92			72.00	145	70	80	160	70	84
				Day 7	05/02/92			72.00	150	80	88	145	60	92
				Day 14	12/02/92			74.00	140	80	88	140	80	72
				Day 21	19/02/92			74.00	135	80	86	140	80	70
				Day 28	26/02/92			73.00	140	80	70	140	80	78
				Day 42	11/03/92			73.00	145	80	72	140	70	78
454	454	Reboxetine	Male	Screen	12/02/92				145	80	104	150	80	116

9550082

2013

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14

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0
VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE							
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)		
3/1	454	Reboxetine	Male	Day 0	17/02/92			77.00	140	80	86	145	80	86	92	
				Day 7	24/02/92			76.00	135	80	76	140	80	80	80	
				Day 14	29/02/92			76.00	140	80	76	140	80	80	80	
				Day 21	09/03/92			75.00	140	70	76	135	70	80	80	
				Day 28	18/03/92			75.00	140	70	72	130	70	80	80	
3/1	454	Reboxetine	Male	Day 35	25/03/92			75.00	120	80	81	120	80	84		
				Day 42	01/04/92			75.00	130	80	76	120	80	80		
				Screen	26/02/92						100	60	76	100	60	78
				Day 0	11/03/92			58.00	105	60	60	100	60	60	60	
				Day 7	18/03/92			58.00	110	60	60	100	60	60	60	
3/1	455	Placebo	Female	Day 14	25/03/92			58.00	120	60	66	110	60	70		
				Day 21	01/04/92			58.00	110	60	68	110	60	70		
				Day 28	08/04/92			58.00	120	60	68	115	60	74		
				Day 35	15/04/92			58.00	100	70	66	95	70	74		
				Day 42	22/04/92			58.00	105	70	66	100	70	76		
3/2	456	Imipranine	Female	Screen	18/03/92				130	80	88	125	80	92		
				Day 0	25/03/92			47.00	115	70	64	110	70	66		
				Day 7	01/04/92			49.00	110	60	68	110	60	76		
				Day 14	03/04/92			49.00	130	60	88	110	60	96		
3/2	65/A	Reboxetine	Female	Screen	25/01/91				100	80	80	105	80	84		
				Day 0	29/01/91		14	56.50	100	80	80	110	65	84		
				Day 7	05/02/91			55.00	120	60	88	110	55	92		
				Day 14	12/02/91			56.30	110	60	92	80	50	108		
				Day 21	19/02/91			57.00	100	55	80	110	60	80		
3/2	65/A	Reboxetine	Female	Day 28	26/02/91			57.00	105	70	92	105	70	96		
				Day 35	05/03/91			58.00	110	60	92	115	60	104		
				Day 42	12/03/91			58.50	100	60	80	90	50	84		
				Screen	16/07/91						120	80	72	130	80	
				Day 0	17/07/91		16	61.00	120	80	78	140	80	85		
3/3	67	Placebo	Male	Day 7	24/07/91			60.00	120	80	80	140	90	80		
				Day 14	31/07/91			61.00	120	80	72	130	90	76		
				Day 21	07/08/91			62.00	120	80	72	120	80	80		
				Day 28	14/08/91			60.00	140	90	72	140	90	80		
				Day 35	21/08/91			60.00	140	80	72	140	90	80		
3/3	68	Reboxetine	Male	Day 42	28/08/91			61.00	140	80	72	140	90	80		
				Screen	14/01/92						130	80	62	160	100	
				Day 0	20/01/92		15	80.00	150	100	84	140	90	92		
				Day 7	27/01/92			80.00	140	85	80	130	80	84		
				Day 14	03/02/92			80.00	145	90	78	135	85	84		

2014

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15

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing			
3/3	68	Reboxetine	Male	Day 21	10/02/92	36.80		80.00	130	70	62	130	80	68	
				Day 28	17/02/92	37.20		80.00	140	70	68	130	80	72	72
				Day 35	24/02/92	36.70		80.00	130	80	62	150	90	68	80
				Day 42	02/03/92	37.30		80.00	140	70	62	130	80	72	80
69		Placebo	Male	Screen	31/01/92	36.50	15		115	70	76	105	70	84	
				Day 0	03/02/92	36.80		60.00	110	70	72	105	70	80	80
				Day 7	10/02/92	37.30		60.00	130	80	92	120	70	96	96
				Day 14	17/02/92	37.20		59.00	150	90	88	140	90	92	92
				Day 21	24/02/92	36.80		60.00	120	70	72	110	70	89	89
				Day 28	02/03/92	37.40		60.00	125	80	84	110	70	92	92
				Day 35	09/03/92	37.00		60.00	140	90	84	135	85	85	85
				Day 42	16/03/92	36.80		60.00	135	75	80	120	70	92	92
70		Imipramine	Male	Screen	10/04/92	37.20	16		160	90	80	155	100	88	
				Day 0	13/04/92	36.00		77.00	140	90	88	165	100	100	100
				Day 7	21/04/92	37.00		76.00	110	70	88	120	70	80	80
				Day 14	28/04/92	36.80		76.00	120	70	88	135	80	78	78
				Day 21	05/05/92	36.80		75.00	120	70	80	100	70	88	88
				Day 28	12/05/92	36.60		75.00	130	90	80	120	80	88	88
				Day 35	19/05/92	36.80		74.00	130	80	75	110	70	88	88
				Day 42	26/05/92	37.40		74.00	120	80	60	110	70	80	80
71		Imipramine	Female	Screen	14/04/92	37.00	16		100	70	88	90	60	92	
				Day 0	15/04/92	36.90		57.00	135	90	76	125	100	88	88
				Day 7	22/04/92	37.80		57.00	110	60	78	120	70	80	80
				Day 14	29/04/92	36.80		57.00	110	60	80	120	70	82	82
				Day 21	06/05/92	37.20		57.00	120	80	74	120	80	72	72
				Day 28	13/05/92	36.70		57.00	145	90	76	130	80	72	72
				Day 35	20/05/92	37.00		57.00	160	100	80	150	90	72	72
				Day 42	27/05/92	37.30		57.00	155	100	72	145	80	68	68
72		Reboxetine	Male	Screen	21/07/92	37.00	25		140	60	70	130	70	85	
				Day 0	24/07/92	36.50		66.00	145	70	72	130	70	80	80
				Day 7	31/07/92	37.00		67.00	150	80	72	135	70	80	80
				Day 14	07/08/92	37.60		67.50	170	80	100	150	80	120	120
				Day 21	14/08/92	37.50		68.00	120	80	88	120	70	92	92
				Day 28	21/08/92	36.70		69.00	130	80	84	120	70	88	88
				Day 35	28/08/92	37.00		69.00	120	80	76	105	70	88	88
				Day 42	04/09/92	36.70		66.00	140	100	76	125	90	80	80
3/4	79	Imipramine	Female	Screen	01/05/91	36.90	15		115	70	64	110	65		
				Day 0	04/05/91	37.00		50.00	115	65	72	110	75	75	
				Day 7	11/05/91	37.10		49.00	115	75	72	110	75	84	

2015

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)			
									_lying			_standing		
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
3/4	79	Imipramine	Female	Day 14	17/05/91	36.90		50.00	120	80	76	110	85	92
				Day 21	24/05/91	37.00		50.00	120	75	62	115	75	66
				Day 28	31/05/91	37.10		50.00	120	65	62	110	60	64
				Day 35	07/06/91	36.90		50.00	115	65	64	110	60	66
				Day 42	17/06/91	37.00		51.00	110	60	60	105	60	64
80	80	Imipramine	Male	Screen	31/08/91	37.00	15		125	75	62	120	70	62
				Day 0	31/08/91	37.00		68.00	125	75	62	120	70	62
				Day 7	09/09/91	36.90		68.00	125	70	60	120	65	60
				Day 14	17/09/91	37.00		68.50	130	70	60	120	65	60
				Day 21	25/09/91	37.00		68.00	130	75	60	120	70	64
				Screen	16/05/91	36.80	20		120	85	82	130	90	92
				Day 0	17/05/91	36.70		55.00	130	90	84	130	90	
				Day 7	24/05/91	36.70		55.00	135	90	84	130	90	
				Day 14	31/05/91	36.70		55.00	140	90	80	120	80	
				Day 21	07/06/91	36.90		55.00	120	80	80	130	90	
				Day 28	14/06/91	36.90		55.00	125	80	80	130	84	
				Day 35	21/06/91	36.90		56.00	130	90	80	130	84	
				Day 42	28/06/91			57.00	140	90	90	140	100	
81	81	Reboxetine	Female	Screen	17/06/91	36.80	19		130	80	70	140	90	80
				Day 0	17/06/91	36.70		70.00	130	80	70	140	90	80
				Day 7	24/06/91	37.00		71.00	130	80	72	140	90	80
				Day 14	01/07/91	36.90		69.00	140	90	64	145	90	68
				Day 21	08/07/91	36.90		68.00	130	80	78	120	70	80
				Day 28	15/07/91	36.90		69.00	130	80	78	140	80	80
				Day 35	22/07/91	36.90		69.00	135	80	60	140	90	70
				Day 42	29/07/91			69.00	140	90	140	90		
82	82	Placebo	Male	Screen	17/06/91	36.80	19		130	80	70	140	90	80
				Day 0	17/06/91	36.70		70.00	130	80	70	140	90	80
				Day 7	24/06/91	37.00		71.00	130	80	72	140	90	80
				Day 14	01/07/91	36.90		69.00	140	90	64	145	90	
				Day 21	08/07/91	36.90		68.00	130	80	78	120	70	
				Day 28	15/07/91	36.90		69.00	130	80	78	140	80	
				Day 35	22/07/91	36.90		69.00	135	80	60	140	90	
				Day 42	29/07/91			69.00	140	90	140	90		
83	83	Placebo	Male	Screen	17/06/91	37.00	14		120	80	90	120	80	90
				Day 0	17/06/91	37.00		75.00	120	80	90	120	80	80
				Day 7	24/06/91	36.90		75.00	120	70	80	140	80	84
84	84	Reboxetine	Female	Screen	07/10/91	37.00	14		120	70	68	115	65	68
				Day 0	07/10/91	37.00		60.00	135	80	68	115	65	68
				Day 7	14/10/91	36.90		60.00	130	80	64	120	70	66
				Day 14	23/10/91	37.00		60.00	130	75	64	115	65	64
				Day 21	31/10/91	36.90		60.50	120	70	70	115	60	68
				Day 28	07/11/91	37.00		60.50	120	65	60	115	60	64
				Day 35	15/11/91	37.00		61.00	120	70	62	120	65	66
				Day 42	23/11/91	37.00		61.00	125	70	120	70		

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17

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE								
									Lying			Standing					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)			
3/4	85	Imipramine	Female	Screen	25/10/91		17		115	60	100	70					
				Day 0	28/10/91			120	60	110	70						
				Day 7	04/11/91			54.00			140	80	76	145	70	80	
				Day 14	12/11/91			55.00			129	80	76	110	70	84	
				Day 21	18/11/91			56.00			129	80	74	110	70	80	
				Day 28	25/11/91			57.00	125	80	96	115	80	98			
				Day 35	02/12/91			56.50	130	80	82	120	70	88			
				Day 42	09/12/91			57.00	110	70	90	100	60	90			
				86	Imipramine	Male	Screen	03/12/91	37.00	15		140	85	64	135	80	62
							Day 0	03/12/91	37.00		63.00			140	80	64	135
Day 7	11/12/91	37.00					63.00			130	80	60	125	75			
Day 14	18/12/91	37.00					63.00			130	75	60	136	70			
Day 21	24/12/91	37.00					63.00			125	70	62	120	70			
				Day 28	30/12/91	37.00		63.50	125	70	64	120	70	62			
				Day 35	07/01/92	37.00		63.50	120	66	120	65	120	65			
				Day 42	15/01/92	37.00		63.50	90	74	160	100	100	84			
				87	Placebo	Female	Screen	06/12/91		17		120	80	80	115	80	84
							Day 0	09/12/91			61.00			110	80	80	110
Day 7	16/12/91						61.00			110	80	80	100	70			
Day 14	22/12/91						61.00			120	80	84	110	70			
Day 21	29/12/91						63.00			120	80	88	100	60			
				Day 28	06/01/92	61.00		61.00	90	70	160	90	80				
				Day 35	13/01/92	60.00		59.50	140	80	84	160	80	100			
				Day 42	20/01/92	59.50		59.50	140	80	80	130	80	84			
				88	Placebo	Male	Screen	23/03/92	37.00	14		110	60	60	128	70	62
							Day 0	23/03/92	37.00		76.00			120	60	60	128
Day 7	30/03/92	37.00					76.00			130	80	58	125	75			
Day 14	06/04/92	37.00					76.00			125	75	60	120	75			
Day 21	13/04/92	37.00					76.00			120	70	62	120	75			
				Day 28	22/04/92	37.00		76.00	120	75	63	125	75	61			
				Day 35	30/04/92	37.00		75.50	120	70	64	125	80	62			
				Day 42	09/05/92	37.00		76.00	75	62	125	75	60				
				89	Reboxetine	Female	Screen	26/03/92	37.00	14		115	75	60	145	70	58
							Day 0	26/03/92	37.00		51.00			115	75	60	145
Day 7	02/04/92	37.10					50.50			120	75	60	145	70			
Day 14	07/04/92	37.00					51.00			120	70	60	145	70			
Day 21	14/04/92	37.00					50.50			115	70	64	145	75			
				Day 28	21/04/92	36.90		50.60	115	70	63	120	70	64			
				Day 35	28/04/92	37.00		50.80	120	65	120	70	64				
				Day 42	06/05/92	37.00		51.00	115	65	120	70	64				

2017

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18

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE														
									Lying			Standing											
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)									
3/4	90	Reboxetine	Male	Screen	27/04/92																		
				Day 0	27/04/92	15	72.00	120	85	80	150	90	90	90	90	90	90	90	90	90	90	90	
				Day 7	05/05/92		73.00	140	95	80	130	90	90	88	84	84	84	84	84	84	84	84	84
				Day 14	12/05/92		73.00	135	90	80	130	90	90	80	80	80	80	80	80	80	80	80	80
				Day 21	19/05/92		73.00	130	70	80	120	80	80	80	80	80	80	80	80	80	80	80	80
				Day 28	26/05/92		73.00	130	80	80	80	140	90	80	84	84	84	84	84	84	84		
				Day 35	02/06/92		73.00	140	80	80	70	150	90	80	80	80	80	80	80	80	80		
				Day 42	09/06/92		73.00	130	80	70	70	135	80	74	74	74	74	74	74	74	74		
457		Placebo	Female	Screen	18/05/92	37.00																	
				Day 0	21/05/92	17	63.00	120	80	75	130	85	90	90	90	90	90	90	90	90	90	90	
				Day 7	29/05/92		62.00	120	70	80	115	65	90	90	90	90	90	90	90	90	90	90	
				Day 14	06/06/92		37.00	62.00	70	80	105	65	90	90	90	90	90	90	90	90	90	90	
				Day 21	11/06/92		36.90	61.00	70	80	100	60	90	90	90	90	90	90	90	90	90	90	
458		Reboxetine	Female	Screen	18/05/92	37.00																	
				Day 0	26/05/92	18	79.00	120	85	70	110	80	85	85	85	85	85	85	85	85	85	85	
				Day 7	02/06/92		78.00	120	80	70	100	60	90	90	90	90	90	90	90	90	90	90	
				Day 14	09/06/92		78.00	125	85	70	110	65	90	90	90	90	90	90	90	90	90	90	
				Day 21	16/06/92		37.00	78.00	70	80	105	65	90	90	90	90	90	90	90	90	90	90	
459		Placebo	Female	Screen	29/05/92	37.10																	
				Day 0	01/06/92	20	41.00	130	70	80	110	60	90	90	90	90	90	90	90	90	90		
				Day 7	09/06/92		41.00	130	75	80	110	60	90	90	90	90	90	90	90	90	90		
				Day 14	16/06/92		41.00	130	70	80	105	60	90	90	90	90	90	90	90	90	90		
				Day 21	22/06/92		36.90	135	65	75	110	55	90	90	90	90	90	90	90	90	90		
				Day 28	29/06/92		41.00	130	60	70	110	50	85	75	75	75	75	75	75	75			
				Day 35	06/07/92		37.20	135	65	65	110	50	85	75	75	75	75	75	75	75			
				Day 42	13/07/92		36.90	120	60	65	105	55	80	80	80	80	80	80	80	80			
460		Reboxetine	Male	Screen	14/08/92																		
				Day 0	19/08/92	15	62.00	125	89	80	130	85	85	85	85	85	85	85	85	85	85		
				Day 7	26/08/92		62.00	130	80	80	135	80	80	80	80	80	80	80	80	80			
461		Imipramine	Female	Screen	15/09/92	37.00																	
				Day 0	17/09/92	14	79.00	130	70	80	125	70	80	80	80	80	80	80	80	80	80		
				Day 7	24/09/92		79.00	140	75	75	135	70	75	75	75	75	75	75	75	75	75		
462		Imipramine	Female	Screen	29/09/92	37.10																	
				Day 0	29/09/92	13	68.00	130	70	75	125	70	70	70	70	70	70	70	70	70	70		
				Day 7	08/10/92		68.00	125	70	75	125	70	70	70	70	70	70	70	70	70	70		

2018

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing		
4/1	91	Imipramine	Female	Screen	05/10/91	37.20	17	67.00	120	70	70	130	80	65
				Day 0	12/10/91	37.00		67.00	120	70	65	130	80	65
				Day 7	19/10/91	36.80		66.00	120	70	70	120	70	65
				Day 14	26/10/91	37.00		65.00	120	70	70	105	60	76
				Day 21	02/11/91	37.00		64.00	135	80	70	115	80	75
Day 28	09/11/91	37.00		64.00	125	70	70	115	70	75				
Day 35	16/11/91	37.00		64.00										
	92	Reboxetine	Female	Screen	07/08/91	36.80		41.00	120	75	70	120	70	74
				Day 0	07/08/91	36.80		41.00	120	70	70	120	70	74
				Day 7	14/08/91	36.90	14	41.00	100	65	102	110	70	94
				Day 14	21/08/91	36.80		41.00	110	70	92	115	75	86
				Day 21	28/08/91	37.60		40.00	105	70	72	100	65	64
Day 28	04/09/91	37.30		38.00	105	75	70	100	75	68				
Day 35	11/09/91	37.50		38.00	110	85	68	105	85	66				
Day 42	18/09/91	37.40		39.00	120	85	86	115	80	82				
	93	Placebo	Male	Screen	28/06/91	37.00	20	68.00	130	100	64	130	100	66
				Day 0	03/07/91	37.00		68.00	130	80	64	120	90	70
				Day 7	09/07/91	37.00		69.00	130	80	72	130	80	70
				Day 14	17/07/91	37.00		70.00	130	80	80	130	80	68
				Day 21	24/07/91	37.00		70.00	125	90	72	130	80	76
Day 28	31/07/91	37.00		70.00	120	70	60	120	70	66				
Day 35	09/08/91	37.00		71.00	120	80	75	120	90	80				
Day 42	16/08/91	37.00		70.00	120	70	50	120	70	50				
	94	Placebo	Female	Screen	27/06/91	37.00	16	60.00	120	90	72	130	80	76
				Day 0	05/07/91	37.00		60.00	120	90	72	130	80	76
				Day 7	12/07/91	37.00		58.00	130	90	80	130	80	80
				Day 14	16/07/91	37.00		58.00	120	80	80	110	80	80
				Day 21	23/07/91	37.00		58.00	150	80	80	130	90	80
Day 28	30/07/91	37.00		58.00	130	80	80	130	80	80				
Day 35	07/08/91	38.00		58.00	125	80	80	130	80	80				
Day 42	14/08/91	37.00		58.00	120	80	80	120	80	80				
	95	Imipramine	Female	Screen	03/06/91	37.50	20	77.00	110	70	75	110	80	84
				Day 0	03/06/91	37.00		77.00	120	80	72	120	90	76
				Day 7	10/06/91	37.20		77.00	110	80	68	120	80	70
				Day 14	17/06/91	37.00		77.00	130	80	68	130	80	72
				Day 28	02/07/91	37.00		77.00	130	70	75	130	80	70
Day 35	09/07/91	37.00		77.00	130	80	70	120	70	76				
Day 42	17/07/91	37.00		78.00	120	70	70	120	70	76				

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20

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 20.0
 VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									Sitting S.B.P. (mmHg)	Sitting D.B.P. (mmHg)	Sitting Heart Rate (beats/min)	Standing S.B.P. (mmHg)	Standing D.B.P. (mmHg)	Standing Heart Rate (beats/min)
4/1	96	Reboxetine	Female	Screen	27/08/91	37.40			125	85	70	125	80	72
				Day 0	04/09/91	37.40		79.00	125	85	70	125	80	72
				Day 7	11/09/91	37.50		77.00	125	85	70	120	80	74
				Day 14	18/09/91	37.60		76.00	120	80	70	115	75	76
				Day 21	25/09/91	37.50		75.00	140	90	96	140	85	100
	115	Reboxetine	Female	Day 28	02/10/91	37.60		75.00	135	85	88	130	80	90
				Day 35	09/10/91	37.50		75.00	130	80	86	130	80	90
				Day 42	16/10/91	36.70		75.00	125	85	72	130	90	70
				Screen	28/06/92	36.80	16		125	80	76	120	80	78
				Day 0	05/05/92	37.20		76.00	120	80	72	115	75	74
	116	Imipramine	Female	Day 7	12/05/92	37.20		75.50	120	80	80	120	75	82
				Day 14	19/05/92	37.40		74.50	120	80	82	115	75	84
				Day 21	26/05/92	37.20		73.50	120	80	82	125	80	82
				Day 28	02/06/92	37.40		72.50	125	80	80	125	75	82
				Day 35	09/06/92	37.30		72.00	130	90	76	120	85	80
	117	Imipramine	Female	Day 42	16/06/92	37.20		72.00	125	85	78	125	80	80
				Screen	07/05/92	36.80	19		130	80	82	125	75	80
				Day 0	15/05/92	36.80		56.00	125	75	80	125	70	82
				Day 7	23/05/92	36.80		56.00	125	75	82	125	70	82
				Screen	27/08/91	36.90	16		110	65	65	110	60	65
	118	Reboxetine	Female	Day 0	03/09/91	37.20		65.00	140	85	80	135	80	80
				Day 7	10/09/91	37.50		65.00	135	85	86	130	80	80
				Day 14	17/09/91	37.40		66.00	130	80	84	125	80	78
				Day 21	24/09/91	37.50		70.00	130	85	78	125	85	72
				Day 28	01/10/91	37.40		70.00	130	85	72	125	80	70
	119	Placebo	Female	Day 35	08/10/91	37.50		70.00	135	85	76	120	75	70
				Day 42	15/10/91	37.50		70.00	135	85	76	120	75	70
				Screen	15/05/92	36.90	17		120	80	84	120	80	84
				Day 0	22/05/92	37.30		84.00	125	75	94	120	75	84
				Day 7	29/05/92	37.40		84.00	130	75	84	125	70	86
	119	Placebo	Female	Day 14	05/06/92	37.20		84.00	125	75	86	120	75	86
				Day 21	12/06/92	37.20		85.00	125	75	85	120	75	88
				Day 28	19/06/92	37.10		85.00	115	70	82	115	65	82
				Day 35	26/06/92	37.20		85.00	125	75	80	120	75	84
				Day 42	03/07/92	37.10		85.00	115	70	80	115	70	84
	119	Placebo	Female	Screen	16/03/92	36.50		54.00	110	80	120	90	90	
				Day 0	16/03/92	36.50		54.00	110	80	120	90	90	

9550082

2020

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing Heart Rate (beats/min)		
4/1	120	Placebo	Female	Screen	25/07/92	36.80	16	56.00	125	75	60	120	75	62
				Day 0	31/07/92	36.70		56.00	125	75	56	125	70	58
				Day 7	07/08/92	36.70		55.50	130	80	60	125	75	56
				Day 14	17/08/92	36.70		56.00	115	70	56	115	65	56
				Day 21	21/08/92	36.70		56.00	115	70	58	115	70	58
	145	Imipramine	Female	Day 28	28/08/92	36.80		56.00	120	75	56	115	70	58
				Day 35	04/09/92	36.70		56.50	115	70	60	115	70	58
				Day 42	11/09/92	36.70		56.00	125	65	60	125	60	62
				Screen	23/09/92	36.70	15	62.00	125	85	75	125	85	72
				Day 0	29/09/92	36.70		61.50	120	75	76	115	75	80
	146	Placebo	Female	Day 7	06/10/92	36.70		62.00	120	75	76	120	70	76
				Day 14	14/10/92	36.70		61.00	125	80	90	125	75	86
				Day 21	20/10/92	36.80		61.00	115	70	76	115	70	78
				Day 28	27/10/92	36.70		61.00	115	70	76	115	70	78
				Day 35	03/11/92	36.70		61.50	120	80	92	120	80	92
	146	Placebo	Female	Screen	30/08/92	36.70	12	59.00	150	100	90	145	95	88
				Day 0	15/09/92	36.70		59.00	145	80	92	145	75	92
				Day 7	23/09/92	36.70		59.00	145	80	86	145	80	82
				Day 14	29/09/92	36.80		59.50	140	75	88	140	80	86
				Day 21	06/10/92	36.70		57.00	150	100	62	150	95	65
	147	Reboxetine	Female	Day 28	14/10/92	36.90		57.00	150	90	66	145	90	66
				Day 35	20/10/92	37.60		58.00	145	90	68	145	85	66
				Day 42	27/10/92	36.90		58.50	135	80	60	135	75	60
				Screen	18/08/92	36.70	13	96.00	150	80	68	145	80	70
				Day 0	31/08/92	36.80		96.00	150	90	75	145	90	75
	148	Imipramine	Female	Day 7	07/09/92	36.80		97.00	150	85	78	150	85	76
				Day 14	14/09/92	36.70		97.00	145	85	75	145	80	77
				Day 21	21/09/92	37.10		96.00	150	90	75	150	85	75
				Day 28	28/09/92	37.60		96.00	145	85	76	145	85	78
				Day 35	05/10/92	36.70		97.00	150	85	76	150	80	78
	148	Imipramine	Female	Day 42	12/10/92	36.70		97.00	130	75	80	130	80	80
				Screen	21/09/92	36.80	16	77.50	125	85	65	125	80	70
				Day 0	25/09/92	36.80		77.50	125	85	65	125	80	65
				Day 7	02/10/92	36.70		77.00	120	80	65	120	75	67
				Day 14	09/10/92	37.00		77.00	125	85	70	125	85	70
	148	Imipramine	Female	Day 21	16/10/92	36.90		77.00	130	80	85	125	75	85
				Day 28	23/10/92	36.70		77.00	125	80	80	125	70	82
				Day 35	30/10/92	36.90		77.00	125	80	72	120	75	72

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
4/1	148	Imipramine	Female	Day 42	06/11/92	37.10		77.50	140	85	80	140	85	80
	149	Reboxetine	Male	Screen	22/09/92	36.70	14		135	80	68	135	80	70
				Day 0	29/09/92	37.10		74.00	140	80	70	140	80	74
				Day 7	06/10/92	36.90		73.50	140	80	72	135	75	74
				Day 14	13/10/92	36.70		74.00	135	80	70	135	75	70
				Day 21	20/10/92	36.70		73.50	140	85	62	135	85	61
				Day 28	27/10/92	36.90		74.50	140	80	76	140	80	78
				Day 35	03/11/92	36.70		74.00	135	75	80	135	75	80
				Day 42	10/11/92	37.10		74.00	145	90	70	140	85	72
	150	Placebo	Male	Screen	18/09/92	37.00	17		120	80	60	115	75	62
				Day 0	29/09/92	37.00		82.00	120	80	64	120	80	66
				Day 7	06/10/92	36.90		82.00	130	85	66	125	85	66
				Day 14	13/10/92	36.80		82.00	130	85	66	125	85	66
				Day 21	20/10/92	36.80		82.00	130	90	100	130	90	100
				Day 28	27/10/92	36.70		82.00	130	90	92	130	90	92
				Day 35	03/11/92	36.80		82.00	135	90	88	135	90	86
				Day 42	10/11/92	36.20		84.00	125	80	60	125	80	60
4/2	93/A	Placebo	Male	Screen	21/02/91	37.00	22		150	90	90	150	90	90
				Day 0	21/02/91	37.00		100.00	150	90	80	150	90	80
				Day 7	01/03/91	37.00		98.00	130	80	70	120	80	75
				Day 14	08/03/91	37.00		97.00	130	70	80	100	70	95
				Day 21	15/03/91	37.00		97.00	160	80	80	140	80	98
				Day 28	22/03/91	37.00		97.00	150	80	84	140	80	95
				Day 35	29/03/91	37.00		97.00	140	80	80	140	80	85
				Day 42	05/04/91	37.00		97.50	140	80	80	140	80	85
	99/A	Placebo	Male	Screen	26/03/91	37.00	20		120	70	82	120	70	80
				Day 0	26/03/91	37.00		83.00	120	70	82	120	70	92
				Day 7	02/04/91	37.00		83.00	120	70	85	120	70	95
				Day 14	09/04/91	37.00		83.00	120	60	82	120	60	98
				Day 21	16/04/91	37.00		83.00	120	70	75	120	70	82
				Day 28	23/04/91	37.00		85.00	130	80	80	130	70	84
				Day 35	30/04/91	37.00		83.50	120	70	82	120	70	88
	104	Reboxetine	Male	Screen	20/05/91	37.00	20		140	80	80	130	80	82
				Day 0	20/05/91	37.00		82.00	140	80	80	130	80	82
				Day 7	29/05/91	37.00		81.00	130	80	82	120	80	96
				Day 14	04/06/91	37.00		80.00	140	80	90	130	80	98
				Day 21	11/06/91	37.00		80.00	130	60	80	120	60	88
				Day 28	18/06/91	37.00		80.00	130	80	90	120	80	96
				Day 35	25/06/91	37.00		80.00	120	60	90	110	60	98

9550082

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 20.0
 VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing			
4/3	97	Placebo	Male	Screen	11/04/91	37.00	14		130	80	80	130	80	75	
				Day 0	16/04/91	37.00		62.00	130	90	60	130	90	60	60
				Day 7	23/04/91	37.00		62.00	130	80	98	130	80	80	80
				Day 14	30/04/91	37.00		62.00	130	80	90	130	80	80	80
				Day 21	07/05/91	37.00		62.00	130	80	80	130	80	80	80
	98	Reboxetine	Female	Screen	19/06/91	37.00			140	80	80	140	80	90	
				Day 0	19/06/91	37.00		53.00	130	80	90	120	80	80	80
				Day 7	26/06/91	37.00		53.00	140	90	80	130	90	80	80
				Day 14	03/07/91	37.20		52.50	140	90	80	135	90	80	80
				Day 21	10/07/91	37.10		53.00	140	90	80	150	90	80	80
	99	Placebo	Female	Screen	07/08/91	37.00			150	80	90	150	80	80	
				Day 0	07/08/91	37.00		60.00	150	80	90	150	80	80	80
				Day 7	14/08/91	37.00		60.00	150	80	80	150	80	80	80
				Day 14	21/08/91	37.30		60.00	150	80	80	150	80	80	80
				Screen	27/11/91	37.00	20		110	70	80	110	70	80	80
	100	Imipramine	Female	Day 0	27/11/91	37.00		44.00	110	70	80	110	70	90	
				Day 7	03/12/91	37.00		44.00	110	70	80	110	70	90	90
				Day 14	11/12/91	37.20		44.00	120	80	80	120	80	80	90
				Day 21	18/12/91	37.20		44.00	120	80	80	120	80	80	75
				Screen	13/03/92	37.00			120	90	90	120	90	90	90
	101	Imipramine	Male	Day 0	16/03/92	37.00		74.00	120	90	98	120	90	90	
				Day 7	23/03/92	37.00		74.00	120	70	80	120	70	80	80
				Day 14	30/03/92	37.00		74.00	130	90	98	120	90	90	90
				Day 21	06/04/92	37.00		74.00	130	90	80	120	90	80	80
				Day 28	13/04/92	37.00		74.00	130	80	80	120	80	80	80
	109	Reboxetine	Female	Screen	03/06/91	37.30	22		120	70	84	120	60	80	
				Day 0	08/06/91	37.20		59.00	115	75	76	110	70	60	80
				Day 7	15/06/91	37.00		60.00	110	60	76	105	60	60	80
				Day 14	22/06/91	37.10		60.50	110	50	88	100	50	96	96
				Day 21	28/06/91	36.80		60.50	120	80	90	110	70	92	92

9550082

24

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing		
4/4	109	Reboxetine	Female	Day 28	06/07/91	36.90		61.00	80	92	130	90	92	
				Day 35	12/07/91	36.80		61.00	80	84	110	70	84	92
				Day 42	08/08/91			61.00	70	80	105	75	88	88
110	110	Imipramine	Male	Screen	11/06/91	36.80	20	150	90	80	150	100	84	
				Day 0	15/06/91	37.00		66.50	90	84	120	80	88	88
				Day 7	22/06/91	35.60		67.00	70	88	110	70	84	84
				Day 14	29/06/91	36.70		68.00	80	88	110	60	96	96
				Day 21	06/07/91			71.00	70	76	115	70	92	92
				Day 28	13/07/91	37.10		71.00	70	84	115	60	92	92
Day 35	20/07/91	36.80		71.50	70	80	110	80	88	88				
Day 42	26/07/91	36.20		73.00	90	96	150	90	94	94				
111	111	Imipramine	Male	Screen	27/06/91	36.80	27	120	80	78	120	70	86	
				Day 0	03/07/91	37.00		66.00	80	84	120	70	96	96
				Day 7	10/07/91	37.30		66.00	70	92	120	70	80	80
				Day 14	17/07/91	37.00		67.00	70	72	120	80	80	80
				Day 21	24/07/91			66.00	76	88	120	80	68	68
				Day 28	31/07/91	37.50		66.00	120	60	88	90	50	68
				Day 35	07/08/91	36.70		66.00	115	60	68	130	70	68
				Day 42	14/08/91			66.00	110	60	90	100	60	88
112	112	Placebo	Male	Screen	05/07/91	37.10	20	120	70	64	115	70	72	
				Day 0	09/07/91	36.80		65.00	100	66	140	100	76	76
				Day 7	17/07/91	36.90		65.00	130	66	120	70	70	70
				Day 14	24/07/91	36.90		66.00	110	70	140	90	76	76
				Day 21	31/07/91	37.00		66.00	130	70	120	70	78	78
				Day 28	07/08/91			66.00	125	70	110	70	76	76
Day 35	14/08/91			65.00	125	70	66	110	70	72				
Day 42	20/08/91	37.00		66.00	110	60	72	110	70	76				
113	113	Reboxetine	Male	Screen	26/08/91	36.90	18	125	70	64	130	80	76	
				Day 0	30/08/91	36.90		96.00	70	64	130	80	76	76
				Day 7	07/09/91	37.00		95.00	60	76	120	70	80	80
				Day 14	14/09/91	37.10		96.00	90	78	170	100	96	96
				Day 21	23/09/91	37.00		94.00	120	70	120	80	72	72
				Day 28	27/09/91	37.10		94.00	130	90	84	120	84	84
Day 35	05/10/91	37.00		94.00	140	80	80	120	90	84				
Day 42	11/10/91	36.50		94.00	120	60	84	110	80	80				
114	114	Placebo	Female	Screen	19/11/91	36.90	19	170	100	64	165	80	76	
				Day 0	20/11/91	36.70		61.00	80	66	150	90	72	72
				Day 7	27/11/91			61.00	80	68	155	80	76	76
				Day 14	04/12/91			61.00	150	70	150	80	84	84

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25

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/045
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
4/4	114	Placebo	Female	Day 21	11/12/91	36.70		61.00	160	80	60	135	80	64
				Day 28	18/12/91	37.00		61.50	150	90	62	150	85	66
				Day 35	24/12/91	36.70		61.00	160	85	70	150	80	76
	175	Imipramine	Female	Screen	05/02/92		19		120	80	80	115	70	82
				Day 0	13/02/92	37.00		59.00	130	80	84	120	80	80
				Day 7	20/02/92	36.90		61.00	110	80	88	110	80	94
	176	Placebo	Female	Day 14	27/02/92	37.00		60.00	120	90	76	120	80	96
				Day 21	05/03/92			60.00	120	90	72	110	80	90
				Day 28	12/03/92			60.00	110	75	72	105	75	90
	177	Imipramine	Female	Day 35	19/03/92			61.00	130	80	82	110	75	92
				Day 42	25/03/92			62.00	100	70	76	100	70	70
				Screen	11/03/92	36.80		50.00	130	80	66	110	80	90
	178	Reboxetine	Female	Day 0	13/03/92	37.00		50.00	120	80	78	110	80	84
				Day 7	21/03/92			50.00	135	80	72	120	90	80
				Day 14	28/03/92	37.00		50.50	120	75	66	120	80	70
	179	Placebo	Female	Day 21	06/04/92			49.50	140	90	84	120	90	94
				Day 28	10/04/92				150	80				
				Screen	22/04/92	36.80	23	59.00	150	100	70	140	90	78
	180	Reboxetine	Male	Day 0	28/04/92	36.80		71.00	135	100	76	150	100	84
				Day 7	04/05/92	36.40		71.00	160	80	70	140	85	80
				Day 14	11/05/92	36.50		70.00	170	90	82	130	80	90
	179	Placebo	Female	Day 21	18/05/92	36.70		69.00	130	85	78	130	80	84
				Day 28	27/05/92	36.80		68.00	110	70	100	140	90	104
				Day 35	01/06/92				140	100	100	140	90	104
	179	Placebo	Female	Day 42	09/06/92	36.80		68.00	110	70	80	110	80	80
				Screen	07/09/92	36.80	23	64.50	110	60	72	110	70	74
				Day 0	10/09/92	36.80		64.00	120	80	72	130	70	76
	180	Reboxetine	Male	Day 7	17/09/92	36.50		64.00	110	60	72	100	60	68
				Day 14	24/09/92	36.70		63.00	100	50	78	110	70	88
				Day 21	29/09/92	36.80			110	80	70	105	80	72

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26

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE							
									S.B.P. (mmHg)	D.B.P. (mmHg)	Lying Heart Rate (beats/min)	standing Heart Rate (beats/min)				
4/4	180	Reboxetine	Male	Day 0	06/10/92	36.40		69.00	100	70	60	110	80	90		
				Day 7	13/10/92	36.80		69.00	100	70	60	100	80	80	84	
				Day 14	20/10/92			69.00	120	70	72	110	70	80	80	84
				Day 21	27/10/92	36.70		67.50	105	50	64	100	50	60	72	72
				Day 28	03/11/92	36.80		67.50	90	60	64	95	60	60	72	72
5/1	127	Reboxetine	Male	Day 35	10/11/92			67.50	110	70	70	110	80	76		
				Day 42	17/11/92			68.00	120	80	76	130	90	88	88	
				Screen	03/06/91	37.00	20									
				Day 0	05/06/91	37.20		84.00	120	80	80	120	75	80	80	80
				Day 7	13/06/91	37.00		82.00	120	80	80	120	80	80	80	80
128	128	Reboxetine	Female	Day 14	20/06/91	36.80		83.00	130	80	92	125	80	96		
				Day 21	27/06/91	37.00		84.00	120	70	84	120	65	90	90	
				Day 28	04/07/91	36.80		84.00	140	80	80	130	75	90	90	
				Day 35	11/07/91	37.20		84.00	120	75	90	115	75	90	90	
				Day 42	18/07/91	37.20		85.00	120	80	90	110	80	100	100	
129	129	Placebo	Male	Screen	10/06/91	37.00	22									
				Day 0	13/06/91	37.20		54.00	125	80	80	120	75	90	90	
				Day 7	21/06/91	37.20		54.00	110	75	90	115	80	80	80	
				Day 14	28/06/91	37.10		55.00	100	70	80	100	65	80	80	
				Day 21	05/07/91	36.80		54.60	120	80	84	110	75	90	90	
129	129	Placebo	Male	Day 28	12/07/91	37.00		55.00	115	75	84	100	75	90		
				Day 35	19/07/91	37.00		54.50	115	80	90	110	85	100	100	
				Day 42	26/07/91	37.30		53.50	115	70	90	110	70	90	90	
				Screen	23/12/91	37.00	14									
				Day 0	30/12/91	37.00		55.00	120	70	72	100	60	72	72	
130	130	Placebo	Male	Day 7	30/12/91	37.00		55.00	120	70	72	100	60	72		
				Day 14	06/01/92	37.00		54.00	120	70	80	120	70	70	70	
				Day 21	13/01/92	37.00		56.00	120	70	70	120	70	70	70	
				Day 28	20/01/92	37.00		56.00	130	80	80	130	70	80	80	
				Day 35	27/01/92	37.00		56.00	120	70	72	120	70	70	70	
130	130	Placebo	Male	Day 42	03/02/92	37.00		55.00	120	70	72	120	70	72		
				Screen	04/03/92	37.00	18									
				Day 0	04/03/92	37.00		58.00	100	60	70	100	60	70	78	
				Day 7	11/03/92	37.00		58.00	120	70	72	110	70	70	70	
				Day 14	18/03/92	37.00		58.00	130	80	79	120	60	70	78	
130	130	Placebo	Male	Day 21	25/03/92	37.00		58.00	120	70	76	110	70	78		
				Day 28	01/04/92	37.00		59.00	110	70	76	110	70	72	72	
				Day 35	08/04/92	37.00		59.00	110	60	80	100	60	80	80	
				Day 42	15/04/92	37.00		59.00	120	70	80	120	60	80	80	

2026

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27

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing (beats/min)			
5/1	131	Imipramine	Female	Screen	20/03/92	37.00	14	81.00	110	60	66	100	60	64	
				Day 0	20/03/92	37.00		81.00	110	60	70	100	60	66	
				Day 7	27/03/92	37.00		81.00	120	100	70	100	70	70	
				Day 14	03/04/92	37.00		76.00	140	110	70	80	110	70	80
				Day 21	10/04/92	37.00		80.00	120	110	70	80	110	70	80
				Day 28	17/04/92	37.00		79.00	115	110	70	72	110	70	72
	132	Imipramine	Male	Screen	23/06/92	37.00	16	83.00	140	80	80	140	80	80	
				Day 0	25/06/92	36.80		83.00	150	90	80	150	90	84	
				Day 7	02/07/92	36.70		84.00	160	90	78	160	90	84	
				Day 14	09/07/92	37.00		84.00	160	80	80	160	80	84	
				Day 21	16/07/92	37.00		83.00	160	80	64	160	80	72	
				Day 28	23/07/92	37.00		83.00	150	90	80	140	80	88	
5/2	121	Imipramine	Female	Screen	13/12/91	36.80	20	45.00	110	65	72	105	60	78	
				Day 0	20/12/91	36.80		44.00	110	60	76	105	60	78	
				Day 7	27/12/91	36.80		44.00	110	80	72	140	90	80	
				Day 14	03/01/92	36.80		42.50	120	80	56	110	60	84	
				Day 21	10/01/92	36.70		42.00	110	70	66	105	60	78	
				Day 28	19/01/92	36.80		42.00	120	60	88	130	65	92	
5/3	125	Reboxetine	Male	Screen	22/01/91	36.50	14	74.00	140	65	84	130	70	92	
				Day 0	28/01/91	37.00		74.00	135	80	60	135	90	70	
				Day 7	04/02/91	37.40		72.00	135	70	68	120	70	73	
				Day 14	11/02/91	37.20		72.00	110	70	76	120	70	108	
				Day 21	18/02/91	37.00		72.00	110	70	92	110	70	120	
				Day 28	25/02/91	37.00		75.00	140	80	84	120	70	90	
5/3	133	Placebo	Male	Screen	25/11/91	36.50		74.00	120	80	80	110	70	88	
				Day 0	29/11/91	37.00		69.00	120	70	76	160	80	80	
				Day 7	06/12/91	36.90		69.00	130	60	68	125	55	80	
				Day 14	13/12/91	37.00		70.00	135	80	88	130	80	86	
				Screen	02/12/91	37.00		47.00	110	60	68	110	55	72	
				Day 0	06/12/91	36.90		48.00	115	65	74	110	65	79	
5/3	134	Reboxetine	Female	Day 7	13/12/91	37.00		48.00	110	70	84	110	60	88	
				Day 14	20/12/91	37.00		50.00	110	60	76	110	60	80	

2027

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28

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	
5/3	134	Reboxetine	Female	Day 21	27/12/91			47.00	110	55	72	105	55	76	
				Day 42	16/01/92			49.00	110	60	84	100	50	78	
	135	Imipramine	Female	Screen	06/01/92	37.50	22	76.00	150	80	82	150	80	86	
				Day 0	10/01/92	37.50		74.00	150	80	82	150	80	88	
				Day 7	16/01/92	37.50		74.00	150	80	80	150	80	80	
				Day 14	23/01/92			74.00	125	65	68	125	60	66	
				Day 28	06/02/92			77.00	140	90	84	130	80	80	
				Day 35	13/02/92			78.00	150	90	88	140	80	82	
	136	Imipramine	Female	Screen	21/02/92	37.30		79.00	150	90	86	130	80	80	
				Day 0	02/03/92			74.00	115	60	66	125	60	72	
				Day 7	09/03/92			73.00	110	60	72	115	60	72	
				Day 14	16/03/92			74.00	110	70	80	110	70	80	
				Day 28	30/03/92			75.00	110	60	82	100	50	78	
				Day 35	06/04/92			75.00	110	60	82	100	50	78	
	137	Reboxetine	Female	Screen	11/05/92			44.50	110	60	64	95	50	64	
				Day 0	14/05/92			44.00	110	60	76	110	60	78	
				Day 7	21/05/92			43.00	110	70	60	100	65	79	
				Day 14	29/05/92			43.00	120	60	64	110	50	64	
				Day 21	05/06/92			44.00	120	70	64	110	75	75	
				Day 28	11/06/92			43.00	105	70	70	100	70	84	
	138	Placebo	Female	Screen	14/05/92			61.00	110	60	63	110	60	72	
				Day 0	15/05/92			61.00	110	60	68	110	60	72	
				Screen	13/01/92			37.00	13	55.00	160	80	88	140	84
				Day 0	21/01/92			37.00		55.00	160	80	88	140	84
				Day 7	28/01/92			37.00		55.00	120	90	100	65	64
				Screen	17/02/92			37.00	16	67.40	160	90	76	120	80
6/1	151	Imipramine	Male	Day 0	24/02/92	37.00		67.40	130	80	74	130	80	74	
				Day 7	02/03/92	37.00		67.30	160	100	72	165	100	88	
				Day 14	09/03/92	37.00		67.00	150	100	78	140	95	82	
				Day 21	16/03/92	37.00		66.00	150	95	80	140	90	80	
				Day 28	22/03/92	37.00		65.00	150	90	76	140	90	80	
				Day 35	31/03/92	37.50		66.00	150	95	76	150	90	84	
	152	Reboxetine	Female	Screen	07/04/92	37.00		67.00	145	85	66	140	90	66	
				Day 0	24/02/92			67.40	130	80	74	130	80	74	
				Day 7	02/03/92			67.30	160	100	72	165	100	88	
				Day 14	09/03/92			67.00	150	100	78	140	95	82	
				Day 21	16/03/92			66.00	150	95	80	140	90	80	
				Day 28	22/03/92			65.00	150	90	76	140	90	80	
	152	Reboxetine	Female	Day 35	31/03/92	37.50		66.00	150	95	76	150	90	84	
				Day 42	07/04/92	37.00		67.00	145	85	66	140	90	66	

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing D.B.P. (mmHg)	Heart Rate (beats/min)	
6/1	153	Reboxetine	Male	Screen	04/03/91	37.20	12	75.00	120	90	72	125	100	75
				Day 0	18/03/91	37.00		75.00	120	90	72	125	100	75
				Day 7	25/03/91	37.00		75.00	135	80	80	135	100	80
				Day 14	02/04/91			75.00	140	90	80	140	90	80
				Day 21	08/04/91			76.00	135	90	70	140	100	70
				Day 28	15/04/91			76.00	130	70	70	135	95	75
				Day 35	22/04/91			76.00	140	90	70	140	90	70
				Day 42	29/04/91			76.00	135	85	60	140	90	65
				Screen	25/03/92	37.00	17	57.00	130	80	80	125	80	80
				Day 0	30/03/92	37.00			130	80	80	130	80	80
	155	Placebo	Male	Screen	01/07/92	37.00	14	76.00	130	80	100	130	85	100
				Day 0	07/07/92	37.00		76.00	135	90	100	130	90	100
				Day 7	15/07/92	37.00		75.00	150	85	90	140	90	90
				Day 14	21/07/92	37.00		76.00	140	80	92	130	80	96
				Day 21	28/07/92	37.00		76.00	140	80	92	140	80	94
				Day 28	04/08/92	37.00		76.00	145	80	96	135	80	96
				Screen	01/09/92	37.40	20		140	80	70	130	70	72
				Day 0	08/09/92	37.40		72.00	130	70	74	130	70	72
				Day 7	15/09/92	37.20		72.00	135	70	74	130	75	72
				Day 14	22/09/92	37.40		71.00	130	70	72	125	70	76
				Day 21	29/09/92	37.30		71.00	120	70	70	120	70	76
				Day 28	06/10/92	37.20		71.00	130	70	72	120	70	74
				Day 35	13/10/92	37.20		70.00	130	70	72	120	75	74
				Day 42	20/10/92	37.40		70.00	110	70	66	110	70	62
				Screen	22/04/91	37.00	15	62.00	140	75	80	140	80	80
6/2	157	Reboxetine	Male	Day 0	29/04/91	37.00		61.00	125	70	84	120	70	86
				Day 7	06/05/91	37.20		60.00	125	70	78	125	75	80
				Day 14	13/05/91	37.20		60.00	130	75	80	130	75	80
				Day 21	21/05/91	37.30		60.00	125	70	76	125	70	80
				Day 28	27/05/91	37.30		60.00	130	80	80	130	80	80
				Day 35	03/06/91	37.00		61.00	130	70	72	135	75	76
				Day 42	10/06/91	37.00		63.00	140	80	76	150	80	80
				Screen	20/11/91	37.30	16	52.00	110	70	80	120	65	76
				Day 0	23/11/91	37.00		52.00	120	70	80	130	70	80
				Day 7	30/11/91	37.00		52.00	110	70	74	100	70	76
				Day 14	07/12/91	37.20		53.00	120	70	76	110	70	80
				Day 21	14/12/91	37.00		53.00	120	70	92	110	70	92

2029

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30

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing		
6/2	158	Imipramine	Female	Day 28	21/12/91	37.00		52.00	120	70	80	125	70	80
				Day 42	06/01/92	37.00		52.00	120	60	80	110	60	84
	159	Imipramine	Male	Screen	08/07/91	37.10	20	89.00	150	90	92	140	84	88
				Day 0	13/07/91	37.10		86.40	150	90	100	140	90	100
				Day 7	26/07/91	38.00		85.20	150	90	84	150	90	80
				Day 14	27/07/91	36.90		85.00	160	100	96	140	80	104
				Day 21	03/08/91	36.90		85.00	140	110	100	160	120	100
				Day 28	10/08/91	37.00		85.00	140	100	92	130	90	96
				Day 35	17/08/91	37.00		84.80	130	100	92	130	90	92
	160	Placebo	Male	Screen	22/11/91	37.50	12	89.00	120	80	75	120	80	82
				Day 0	23/11/91	37.50		90.00	105	60	70	105	60	72
				Day 7	30/11/91	37.40		90.00	110	60	70	140	60	78
				Day 14	07/12/91	37.00		88.40	130	80	70	125	70	70
				Day 21	14/12/91	39.20		88.00	120	70	70	120	70	70
				Day 28	21/12/91	36.90		87.00	130	80	68	120	80	72
				Day 35	28/12/91	36.90		87.00	110	80	60	115	85	64
	161	Reboxetine	Female	Screen	10/02/92	37.00		56.00	120	70	80	125	70	80
				Day 0	19/02/92	37.20		57.00	130	75	80	125	75	82
				Day 7	26/02/92	37.00		57.00	130	70	80	130	70	80
				Day 14	04/03/92	37.00		56.00	120	70	80	120	70	80
				Day 21	11/03/92	37.00		58.00	120	70	82	120	70	82
				Day 28	19/03/92	37.00								
					162	Placebo	Male	Screen	08/07/91	37.00	22	70.00	130	80
Day 0	10/07/91	37.00						70.00	130	80	86	130	80	85
Day 7	13/07/91	37.00												
	169	Imipramine	Female	Screen	09/12/91	37.00	20	52.00	120	80	88	120	80	90
				Day 0	26/12/91	37.00		52.00	120	80	88	120	80	88
				Day 7	02/01/92	37.00		52.00	120	80	85	120	80	85
				Day 14	09/01/92	37.00		52.00	120	80	90	120	80	90
				Day 21	15/01/92	37.00								
	170	Placebo	Male	Screen	17/10/91	37.00	24	88.00	140	90	88	140	80	90
				Day 0	01/11/91	37.00		88.00	140	90	85	140	80	88
				Day 7	08/11/91	37.00								

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31

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PHARMACIA CNS R2D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing		
6/2	171	Imipramine	Female	Screen	27/06/92	37.00	26	52.00	100	60	80	100	60	85
				Day 0	21/07/92	37.00		52.00	100	60	80	100	60	85
				Day 7	28/07/92	37.00		52.00	100	60	80	100	60	87
				Day 14	04/08/92	37.00		52.00	100	60	75	100	50	80
				Day 21	11/08/92	37.00		52.00	130	60	90	110	60	90
	172	Reboxetine	Female	Screen	07/07/92	37.00	25	53.00	110	60	90	130	60	88
				Day 0	07/07/92	37.00		53.00	110	60	90	130	60	88
				Day 7	13/07/92	37.00		53.00	140	80	70	100	50	83
				Day 14	20/07/92	37.00		51.50	140	80	71	105	50	80
				Day 21	27/07/92	37.00		51.00	140	90	75	100	50	90
2001	173	Placebo	Male	Screen	26/06/92	37.00	19	51.00	130	70	70	80	60	80
				Day 0	04/07/92	37.00		75.00	100	70	62	100	70	70
				Day 7	11/07/92	37.00		75.00	100	70	63	100	70	60
				Day 14	18/07/92	37.00		75.00	110	70	64	100	70	65
				Day 21	25/07/92	37.00		75.00	120	70	60	120	70	67
	174	Reboxetine	Male	Screen	04/05/92	37.00	20	75.50	120	70	62	105	70	70
				Day 0	11/05/92	37.00		77.00	140	90	70	140	90	80
				Day 7	18/05/92	37.00		77.00	140	80	80	140	80	80
				Day 14	25/05/92	37.00		77.00	140	90	85	140	90	84
				Day 21	01/06/92	37.00		77.00	150	90	80	130	90	80
6/3	163	Reboxetine	Male	Screen	29/05/91	37.00		77.00	150	90	85	140	80	88
				Day 0	05/06/91	37.00		77.00	150	90	86	140	80	90
				Day 7	12/06/91	37.00		63.00	120	80	80	120	80	80
				Day 14	19/06/91	37.00		63.00	130	70	70	110	70	70
				Day 21	26/06/91	37.00		63.00	130	70	70	110	70	80
	164	Imipramine	Male	Screen	06/10/91	37.00		74.00	130	70	70	130	60	70
				Day 0	11/10/91	37.00		74.00	130	80	60	130	70	60
				Day 7	18/10/91	37.00		74.00	130	80	60	120	70	60
				Day 14	25/10/91	37.00		74.00	130	80	70	120	80	70
				Day 21	31/10/91	37.00		74.00	130	80	70	120	80	70

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32

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE						
									_lying			_standing			
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	
673	164	Imipramine	Male	Day 21	31/10/91	74.00	80	80	65	130	120	70	70	65	
				Day 28	08/11/91	74.00	80	80	60	120	80	60	120	80	60
				Day 35	15/11/91	74.00	80	80	60	130	120	70	70	60	
	165	Imipramine	Female	Screen	08/10/91					80	130	70	70	90	
				Day 0	15/10/91	49.00	90	60	150	130	90	70	70		
				Day 7	22/10/91	49.00	90	60	140	140	90	70	70		
	166	Reboxetine	Female	Screen	16/10/91					60	110	70	70	60	
				Day 0	25/10/91	60.00	70	60	110	120	80	80	60		
				Day 7	30/10/91	60.00	70	80	120	120	80	80	80		
	167	Placebo	Female	Screen	13/11/91					60	130	80	80	60	
				Day 0	18/11/91	55.00	70	60	120	130	80	80	60		
				Day 7	25/11/91	55.00	70	60	120	130	70	70	60		
	168	Placebo	Female	Screen	25/11/91					60	110	60	60	60	
				Day 0	02/12/91	55.00	70	60	110	110	60	60	60		
				Day 7	09/12/91	55.00	70	60	120	120	70	70	60		
	505	Imipramine	Female	Screen	26/11/91					90	115	70	70	90	
				Day 0	03/12/91	80.00	80	90	130	115	70	70	80		
				Day 7	10/12/91	80.00	80	80	120	120	80	80	80		
	506	Placebo	Female	Screen	02/01/92					70	120	80	80	70	
				Day 0	08/01/92	89.00	80	70	130	120	70	70	80		
				Day 7	15/01/92	89.00	70	80	130	120	70	70	80		

2032

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33

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing		
6/3	506	Placebo	Female	Day 14	22/01/92			89.00	130	70	80	120	70	80
				Day 21	29/01/92			89.00	130	80	70	130	90	70
				Day 28	05/02/92			91.00	130	80	80	130	80	80
				Day 35	12/02/92			90.00	130	80	80	130	80	80
		Day 42	19/02/92			90.00	130	80	65	130	80	65		
	507	Imipramine	Female	Screen	06/01/92									
				Day 0	13/01/92			58.00	120	80	75	120	80	75
				Day 7	21/01/92			58.00	120	80	70	120	80	70
				Day 14	27/01/92			58.00	120	80	80	105	80	80
				Day 21	04/02/92			58.00	120	80	80	100	70	80
				Day 28	10/02/92			59.00	110	80	80	105	80	80
				Day 35	17/02/92			59.00	115	80	80	105	80	80
				Day 42	24/02/92			59.00	115	80	80	105	80	80
	508	Reboxetine	Female	Screen	28/01/92	37.00								
				Day 0	04/02/92			60.00	120	70	80	100	60	80
				Day 7	11/02/92			60.00	120	70	80	110	60	80
				Day 14	18/02/92			60.00	120	70	80	110	60	80
				Day 21	25/02/92			60.00	130	70	100	120	80	100
				Day 28	04/03/92			60.00	130	70	80	120	80	80
				Day 35	10/03/92			60.00	120	70	100	110	70	100
				Day 42	17/03/92			60.00	120	70	100	100	70	100
	509	Placebo	Male	Screen	17/02/92	37.00								
				Day 0	24/02/92			52.00	110	80	58	110	70	80
				Day 7	02/03/92			52.00	120	80	80	110	70	80
				Day 14	09/03/92			52.00	120	80	80	110	70	80
				Day 21	16/03/92			52.00	120	80	70	110	80	70
				Day 28	23/03/92			53.00	120	80	70	110	70	70
				Day 35	30/03/92			53.00	110	70	70	110	70	70
				Day 42	06/04/92			53.00	110	70	64	110	70	70
	510	Reboxetine	Female	Screen	14/02/92	37.00								
				Day 0	26/02/92			55.00	120	70	70	120	70	70
				Day 7	04/03/92			55.00	110	80	70	100	70	70
				Day 14	11/03/92			55.00	110	80	80	100	80	80
	511	Imipramine	Female	Screen	18/03/92									
				Day 0	18/03/92			68.00	130	80	82	130	80	80
				Day 7	25/03/92			68.00	120	70	80	110	70	80
				Day 14	31/03/92			68.00	120	70	70	120	70	80
				Day 21	07/04/92			68.00	150	90	110	150	90	110
		Day 28	13/04/92			68.00	120	70	80	120	70	80		

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34

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Lying D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	standing D.B.P. (mmHg)
6/3	511	Imipramine	Female	Day 35	22/04/92			68.00	120	70	80	120	70	80	80
	512	Placebo	Female	Screen Day 0	24/03/92	36.50		45.00	130	80	70	130	80	70	70
				Day 7	07/04/92			45.00	130	80	80	130	80	80	80
	513	Imipramine	Female	Screen Day 0	04/05/92	37.00		55.00	130	90	90	130	90	90	90
				Day 7	19/05/92			55.00	130	80	80	130	80	80	80
				Day 14	27/05/92			55.00	130	70	70	120	70	70	70
				Day 21	02/06/92			55.00	130	80	108	130	80	108	108
				Day 28	09/06/92			55.00	130	80	100	130	80	100	100
				Day 35	16/06/92			55.00	120	70	80	110	70	80	80
				Day 42	23/06/92			55.00	130	80	100	130	80	100	100
7/02	181	Reboxetine	Male	Screen Day 0	17/01/92	36.60	18	65.00	130	80	60	140	80	64	64
				Day 7	27/01/92	36.60		65.00	120	80	60	130	80	68	68
				Day 14	03/02/92	36.60		85.00	120	80	64	130	75	72	72
				Day 21	10/02/92	36.70		85.00	120	80	60	130	80	72	72
				Day 28	17/02/92	36.60		85.00	120	80	60	130	80	72	72
				Day 35	24/02/92	36.70		85.00	125	80	64	130	80	72	72
				Day 42	02/03/92	36.60		85.00	120	80	64	130	80	76	76
					09/03/92	36.70		86.00	125	85	60	130	80	68	68
	182	Placebo	Male	Screen Day 0	22/11/91	36.90	18	64.00	145	100	76	150	100	84	84
				Day 7	29/11/91	36.90		62.00	150	100	76	150	100	84	84
				Day 14	06/12/91	36.80		63.00	140	90	84	160	110	88	88
				Day 21	13/12/91	36.90		66.50	160	110	76	165	115	88	88
				Day 28	20/12/91	36.60		66.00	160	105	75	165	120	80	80
				Day 35	27/12/91	36.40		66.50	160	100	80	170	105	84	84
				Day 42	03/01/92	36.90		66.00	155	100	78	165	105	84	84
	183	Imipramine	Male	Screen Day 0	30/12/91	36.60	18	93.00	140	95	60	140	105	66	66
				Day 7	31/12/91	36.60		93.00	140	95	60	140	105	66	66
				Day 14	08/01/92	36.90		92.00	130	90	80	140	95	84	84
				Day 21	15/01/92	36.80		92.00	140	95	66	160	100	74	74
				Day 28	22/01/92	36.90		92.00	145	100	72	165	105	80	80
	184	Imipramine	Female	Screen Day 0	17/01/92	36.70	16	60.00	120	80	72	125	80	76	76
				Day 7	27/01/92	36.80		60.00	115	80	68	125	80	76	76
				Day 14	03/02/92	36.80		60.00	120	80	68	130	80	76	76
				Day 21	10/02/92	36.90		60.00	120	80	72	130	85	80	80

2034

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35

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (KG)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
7/02	184	Imipramine	Female	Day 21	17/02/92	36.80		60.00	110	70	64	125	80	80
				Day 28	24/02/92	36.80		61.00	110	75	68	120	80	76
				Day 35	02/03/92	36.80		61.00	115	80	68	125	80	80
185	Reboxetine	Male	Screen	09/04/92	36.20	17		155	110	80	160	105	96	
			Day 0	09/04/92	36.20		73.40	155	110	80	160	105	96	
			Day 7	16/04/92	36.20		72.80	160	100	80	150	105	92	
			Day 14	23/04/92	36.00		73.50	130	80	75	150	95	87	
			Day 21	30/04/92	37.10		73.00	135	85	86	150	100	92	
			Day 28	07/05/92	36.90		73.00	150	110	85	155	110	92	
186	Placebo	Male	Screen	15/04/92	36.70	15		150	95	66	160	110	80	
			Day 0	15/04/92	36.70		67.00	150	95	58	160	110	64	
			Day 7	22/04/92	36.80		66.40	120	90	72	160	105	80	
			Day 14	29/04/92	36.60		66.80	120	95	70	160	110	82	
			Day 21	06/05/92	36.50		66.60	120	90	60	150	100	78	
			Day 28	13/05/92	36.60		66.80	110	70	60	130	95	84	
535	Placebo	Male	Screen	15/04/92	37.50	20		105	65	56	110	70	60	
			Day 0	15/04/92	37.50		85.00	105	65	56	110	70	60	
			Day 7	22/04/92	36.90		85.00	105	65	60	110	70	68	
			Day 14	29/04/92	36.80		86.00	110	70	56	110	65	60	
			Day 21	06/05/92	36.80		86.00	130	80	60	140	80	68	
			Day 28	13/05/92	36.70		86.50	120	80	56	125	80	64	
536	Reboxetine	Female	Screen	08/05/92	36.80	20		135	85	64	135	85	72	
			Day 0	08/05/92	36.80		80.00	135	85	64	135	85	72	
			Day 7	15/05/92	36.80		81.00	120	80	60	140	85	68	
			Day 14	22/05/92	36.80		81.00	120	80	68	135	80	76	
			Day 21	29/05/92	36.80		81.00	120	80	68	130	80	72	
			Day 28	05/06/92	36.70		82.00	120	80	64	130	80	72	
7/03	187	Imipramine	Female	Screen	11/02/92	36.30	16		140	80	76	150	80	80
				Day 0	18/02/92	36.30		77.00	140	80	80	150	80	76
				Day 7	25/02/92	36.20		75.00	140	80	74	140	90	72
				Day 14	03/03/92	36.10		76.00	110	75	70	110	80	70
				Day 21	10/03/92	36.30		76.00	120	70	70	120	70	72
				Day 28	17/03/92	36.30		76.00	120	70	70	120	70	72

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2035

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36

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Lying Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	standing Heart Rate (beats/min)
7/03	187	Imipramine	Female	Day 28	17/03/92	36.40		77.00	140	80	70	145	80	74
				Day 35	24/03/92	36.40		75.00	135	85	78	140	90	80
				Day 42	31/03/92	36.30		77.00	150	90	78	150	95	80
188	188	Placabo	Male	Screen	18/02/92	36.70	14		110	80	70	115	70	70
				Day 0	25/02/92	37.00		70.00	110	70	74	110	70	76
				Day 7	03/03/92	36.60		71.00	125	80	78	135	80	80
				Day 14	10/03/92	36.60		69.50	125	80	72	130	80	76
				Day 21	17/03/92	36.70		69.50	130	80	76	130	80	78
				Day 28	24/03/92	36.60		70.00	125	80	76	130	80	78
				Day 35	31/03/92	36.50		70.00	135	70	76	140	70	78
Day 42	07/04/92	36.30		69.00	115	70	76	120	70	78				
189	189	Placabo	Male	Screen	18/02/92	36.00	15		125	80	70	130	80	72
				Day 0	25/02/92	36.10		86.00	105	65	72	110	70	74
				Day 7	03/03/92	36.30		86.00	105	65	74	110	70	76
				Day 14	10/03/92	36.80		86.00	120	80	74	120	86	76
				Day 21	17/03/92	36.50		88.00	120	80	72	130	80	78
				Day 28	24/03/92	36.40		89.00	135	80	78	140	80	80
				Day 35	31/03/92	36.50		89.00	120	80	78	120	80	80
Day 42	07/04/92	36.50		88.00	120	80	78	125	80	80				
190	190	Reboxetine	Male	Screen	21/02/92	36.40	15		110	80	71	110	80	70
				Day 0	28/02/92	36.70		80.00	130	80	71	130	80	72
				Day 7	06/03/92	36.40		80.00	120	80	71	130	80	71
				Day 14	13/03/92	36.50		80.00	120	80	78	120	80	80
				Day 21	20/03/92	36.60		80.00	120	80	71	120	80	78
				Day 28	27/03/92	36.60		80.00	120	80	70	120	80	72
				Day 35	03/04/92	36.40		79.00	120	80	70	120	80	72
Day 42	10/04/92	36.50		78.00	120	80	72	120	80	74				
191	191	Imipramine	Female	Screen	25/02/92	37.00	16		130	90	84	125	85	88
				Day 0	03/03/92	36.40		84.00	135	85	74	140	90	78
				Day 7	10/03/92	36.70		84.00	135	85	80	140	90	86
				Day 14	17/03/92	36.50		85.00	140	80	76	140	85	78
				Day 21	24/03/92	36.90		83.00	135	80	78	140	80	80
				Day 28	31/03/92	36.70		82.00	130	80	72	140	70	71
Day 35	07/04/92	36.60		82.00	130	85	72	130	90	74				
192	192	Reboxetine	Female	Screen	03/03/92	36.90	16		140	80	80	135	75	84
				Day 0	10/03/92	36.60		82.00	120	80	71	120	80	73
				Day 7	17/03/92	36.30		82.00	120	80	70	125	80	72
				Day 14	24/03/92	36.30		80.00	120	80	72	120	80	74
Day 21	31/03/92	36.40		81.00	135	80	72	140	80	74				

2036

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37

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	
7/03	192	Reboxetine	Female	Day 23	07/04/92	36.40		80.00	130	80	74	130	80	80	74
				Day 35	14/04/92	36.50		80.00	140	100	80	140	100	80	82
				Day 42	21/04/92	36.50		80.00	130	80	80	130	80	80	82
	523	Reboxetine	Female	Screen	28/04/92	36.90	16		105	70	78	100	70	70	78
				Day 0	05/05/92	36.40		52.00	100	70	76	100	70	70	74
				Day 7	12/05/92	36.40		52.00	110	78	75	110	70	70	73
				Day 14	19/05/92	36.50		52.00	110	70	75	110	70	70	78
				Day 21	26/05/92	36.80		52.00	110	70	60	115	78	78	64
				Day 28	02/06/92	36.80		53.00	110	70	64	120	78	68	68
Day 35				09/06/92	36.50		55.00	110	80	64	120	80	68	68	
Day 42				16/06/92	36.40		55.00	105	70	64	110	70	70	68	
524				Placebo	Female	Screen	28/04/92	36.70	15		110	80	66	115	75
	Day 0	05/05/92	36.80				52.00	110	80	66	115	75	76	76	
	Day 7	12/05/92	36.60				52.00	110	80	68	105	70	72	76	
	Day 14	19/05/92	36.50				50.00	105	70	72	110	70	75	75	
	Day 21	26/05/92	36.40				50.00	105	70	72	110	70	75	75	
	Day 28	02/06/92	36.80				50.00	105	70	72	110	70	74	74	
	Day 35	09/06/92	36.40				50.00	105	70	79	110	70	74	74	
	Day 42	16/06/92	36.60				50.00	105	65	72	110	70	74	74	
	525	Placebo	Female			Screen	28/04/92	36.80	15		110	70	78	110	70
Day 0				05/05/92	36.60		91.00	110	70	78	110	70	80	80	
Day 7				12/05/92	36.60		91.00	110	70	76	110	70	78	78	
Day 14				19/05/92	36.60		91.00	110	70	76	110	70	78	78	
Day 21				26/05/92	36.50		91.00	120	80	76	125	80	78	78	
Day 28				02/06/92	36.80		91.00	120	80	72	120	85	76	76	
Day 35				09/06/92	36.70		91.00	120	70	76	115	80	78	78	
Day 42				16/06/92	36.40		90.00	110	70	76	115	80	78	78	
526				Reboxetine	Female	Screen	28/04/92	36.20	16		130	90	76	130	90
	Day 0	05/05/92	36.70				97.00	130	90	76	130	90	78	78	
	Day 7	12/05/92	36.60				96.00	130	80	76	130	80	78	78	
	Day 14	19/05/92	36.80				96.00	130	80	76	130	80	78	78	
	Day 21	26/05/92	36.80				95.00	110	80	74	120	80	78	78	
	Day 28	02/06/92	36.60				97.00	130	80	75	130	80	77	76	
	Day 35	09/06/92	36.40				95.00	130	100	73	140	100	76	76	
	Day 42	16/06/92	36.40				95.00	130	100	75	135	100	78	78	
	527	Imipramine	Female			Screen	12/05/92	36.50	16		120	80	75	120	80
Day 0				19/05/92	36.50		68.00	120	80	75	120	80	77	77	
Day 7				26/05/92	36.50		59.00	115	80	75	120	80	78	78	
Day 14				02/06/92	36.50		59.00	110	70	75	120	70	70	70	

2037

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38

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PIRAMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 20.0
 VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing			
7/03	527	Imipramine	Female	Day 21	09/06/92	36.70		58.00	110	70	72	120	80	74	
				Day 28	16/06/92	36.50		66.00	100	60	76	110	70	78	78
				Day 35	23/06/92	36.50		60.00	110	70	74	120	80	77	76
7/04	193	Placebo	Female	Screen	12/05/92	36.50	16	64.00	160	86	76	120	80	78	
				Day 0	19/05/92	36.50		64.00	120	80	76	120	80	78	78
				Day 7	26/05/92	36.50		55.00	110	70	74	110	70	76	76
7/04	194	Placebo	Female	Day 14	02/06/92	36.50		55.00	110	70	68	115	70	70	
				Day 21	09/06/92	36.50		55.00	110	70	68	115	70	70	70
				Day 28	16/06/92	36.40		55.00	110	70	68	115	70	70	70
7/04	194	Reboxetine	Male	Day 35	23/06/92	36.80		55.00	110	70	72	110	75	76	
				Day 42	30/06/92	36.80		61.00	120	88	64	115	85	72	72
				Screen	25/01/92	36.70	21	61.00	120	82	64	115	85	72	72
7/04	194	Reboxetine	Male	Day 7	01/02/92	36.60		60.00	130	80	82	130	85	72	
				Day 14	08/02/92	36.80		60.00	130	70	82	135	70	80	80
				Day 21	15/02/92	36.80		61.00	130	80	72	125	80	80	72
7/04	194	Reboxetine	Male	Day 28	22/02/92	36.50		60.50	140	70	64	135	80	72	
				Day 35	29/02/92	36.30		60.70	130	80	80	120	75	78	78
				Day 42	07/03/92	36.50		61.00	130	70	64	140	80	72	72
7/04	194	Reboxetine	Male	Screen	25/01/92	36.60	19	78.00	120	80	72	120	90	75	
				Day 0	23/01/92	36.60		78.00	120	80	72	120	90	75	75
				Day 7	01/02/92	36.80		78.00	140	70	64	135	75	72	72
7/04	195	Placebo	Female	Day 14	08/02/92	36.90		78.00	130	80	72	130	80	80	
				Day 21	15/02/92	36.80		77.50	130	80	68	125	75	80	80
				Day 28	22/02/92	36.50		77.00	120	70	72	115	80	80	80
7/04	195	Placebo	Female	Day 35	29/02/92	36.80		77.50	130	70	64	125	80	72	
				Day 42	07/03/92	36.60		78.00	130	80	64	125	80	72	72
				Screen	25/01/92	36.80	20	67.00	130	70	64	125	75	72	72
7/04	196	Reboxetine	Female	Day 0	25/01/92	36.80		67.00	130	70	64	125	75	72	
				Day 7	01/02/92	36.50		67.00	160	70	68	135	75	72	72
				Day 14	08/02/92	36.60		67.00	160	70	68	135	75	72	72
7/04	196	Reboxetine	Female	Day 21	15/02/92	36.60		67.30	160	80	74	130	85	80	
				Day 28	22/02/92	36.50		67.80	160	70	68	130	85	80	80
				Day 35	29/02/92	36.70		68.00	130	50	87	125	95	92	92
7/04	196	Reboxetine	Female	Day 42	07/03/92	36.70		68.00	140	70	68	130	70	84	
				Screen	01/02/92	36.50	18	67.00	120	70	68	115	75	74	74
				Day 0	01/02/92	36.50		67.00	120	70	68	115	75	74	74
7/04	196	Reboxetine	Female	Day 7	08/02/92	36.50		66.50	140	70	68	130	80	72	
				Day 14	15/02/92	36.60		66.50	130	80	64	125	85	85	85

2038

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39

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
7/04	196	Reboxetine	Female	Day 21	22/02/92	36.50		66.70	130	80	72	125	85	80
				Day 28	29/02/92	36.70		67.00	140	70	72	135	75	80
				Day 35	07/03/92	36.60		67.10	130	70	86	140	75	80
				Day 42	14/03/92	36.50		67.50	130	80	81	120	70	90
197	197	Imipramine	Male	Screen	01/02/92	36.50	22		130	80	64	120	85	68
				Day 0	01/02/92	36.50		79.00	130	80	64	120	85	68
				Day 7	08/02/92	36.80		79.00	130	80	67	125	85	72
				Day 14	15/02/92	36.50		78.60	140	80	72	140	85	80
				Day 21	22/02/92	36.70		78.80	140	80	72	135	85	80
				Day 28	29/02/92	36.50		79.20	120	70	72	115	80	80
				Day 35	07/03/92	36.60		79.00	140	70	82	135	80	72
				Day 42	14/03/92	36.50		79.40	130	80	81	130	85	87
198	198	Imipramine	Female	Screen	01/02/92	36.80	18		130	90	74	125	95	80
				Day 0	01/02/92	36.80		61.00	130	90	74	125	95	80
				Day 7	08/02/92	36.50		61.00	140	70	72	135	72	80
				Day 14	15/02/92	36.50		60.30	145	90	72	140	90	84
				Day 21	22/02/92	36.80		60.50	130	80	64	125	85	72
				Day 28	29/02/92	36.90		60.60	130	70	64	120	80	72
				Day 35	07/03/92	36.60		60.90	130	70	80	120	80	84
				Day 42	14/03/92	36.60		70.10	120	70	72	115	75	84
199	199	Imipramine	Male	Screen	28/03/92	36.80	20		130	70	64	125	75	72
				Day 0	28/03/92	36.80		78.00	130	70	64	125	75	72
				Day 7	04/04/92	36.60		78.00	140	70	64	135	70	64
				Day 14	11/04/92	36.60		77.60	140	80	72	140	85	80
				Day 21	18/04/92	36.80		78.00	130	80	68	130	75	72
				Day 28	25/04/92	36.60		78.30	140	80	72	130	84	80
				Day 35	02/05/92	36.60		79.00	130	80	72	130	85	72
				Day 42	09/05/92	36.50		79.20	130	80	84	125	84	90
200	200	Placebo	Male	Screen	28/03/92	36.40	21		130	80	64	125	85	72
				Day 0	28/03/92	36.40		89.00	130	80	64	125	85	72
				Day 7	04/04/92	36.70		88.90	140	70	64	135	75	82
				Day 14	11/04/92	36.50		89.10	140	80	72	180	85	80
				Day 21	18/04/92	36.80		89.00	150	80	72	160	70	64
				Day 28	25/04/92	36.60		89.80	130	70	65	130	75	72
				Day 35	02/05/92	36.60		88.90	140	70	72	135	75	80
				Day 42	09/05/92	36.70		89.00	120	70	68	118	72	72
201	201	Reboxetine	Female	Screen	28/03/92	36.00	24		130	80	72	125	84	80
				Day 0	28/03/92	36.80		79.00	130	80	74	130	75	80
				Day 7	04/04/92	36.40		79.00	130	80	72	125	85	

9550082

41

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	Heart Rate standing (beats/min)			
7/05	206	Imipramine	Female	Day 7	04/02/92	36.30		70.10	145	82	86	140	90	84	
				Day 14	11/02/92	36.00		70.20	140	80	78	145	85	82	82
				Day 21	18/02/92	36.20		70.40	140	85	68	135	80	62	62
				Day 28	25/02/92	36.30		70.50	140	80	64	145	80	67	67
				Day 35	03/03/92	36.40		70.20	140	75	74	140	85	70	70
	Day 42	10/03/92	36.50		70.40	135	70	62	140	80	64	64			
	207	Imipramine	Female	Screen	21/01/92	36.40	17		110	70	62	115	75	60	
				Day 0	28/01/92	36.20		72.00	115	70	68	110	75	65	65
				Day 7	04/02/92	36.40		72.30	110	70	64	110	70	64	64
				Day 14	11/02/92	36.30		72.30	110	70	68	115	70	72	72
				Day 21	18/02/92	36.40		72.10	110	65	62	110	70	67	67
	Day 28	25/02/92	36.20		72.30	115	70	67	110	70	70	70			
	Day 35	03/03/92	36.20		70.30	110	62	70	110	75	65	65			
	Day 42	10/03/92	36.50		70.90	115	70	64	110	70	68	68			
	208	Reboxetine	Male	Screen	24/01/92	36.60	14		120	80	70	115	85	74	
				Day 0	30/01/92	36.30		75.00	110	70	72	115	75	78	78
				Day 7	06/02/92	36.10		75.30	110	70	68	110	75	70	70
				Day 14	13/02/92	36.30		75.10	115	75	74	110	75	77	77
				Day 21	20/02/92	36.30		75.20	115	80	72	115	75	74	74
	Day 28	27/02/92	36.30		75.40	110	75	70	115	75	75	75			
	Day 35	05/03/92	36.40		75.20	110	70	68	115	75	75	75			
	Day 42	12/03/92	36.30		75.60	115	70	68	115	75	75	76			
	209	Placebo	Male	Screen	29/01/92	36.10	18		130	80	60	135	80	81	
				Day 0	05/02/92	36.20		86.00	125	75	64	135	80	67	67
				Day 7	12/02/92	36.40		86.10	130	80	62	135	80	64	64
				Day 14	19/02/92	36.40		86.00	125	84	67	130	79	69	69
				Day 21	26/02/92	36.10		86.20	135	80	65	130	75	62	62
	Day 28	04/03/92	36.20		86.00	130	80	64	135	75	62	62			
	Day 35	11/03/92	36.40		86.00	140	80	68	135	75	69	69			
	Day 42	18/03/92	36.10		86.30	130	80	61	125	75	67	67			
	210	Reboxetine	Male	Screen	03/02/92	36.00	13		150	90	88	150	95	86	
				Day 0	07/02/92	36.20		76.00	160	90	90	150	95	88	88
				Day 7	14/02/92	36.40		75.90	165	85	88	160	90	85	85
				Day 14	21/02/92	36.50		76.10	150	80	84	150	85	87	87
				Day 21	28/02/92	36.50		76.40	155	85	82	150	90	85	85
	Day 28	06/03/92	36.70		76.60	140	85	76	150	85	79	79			
	Day 35	13/03/92	36.30		76.20	150	85	86	155	90	89	89			
	Day 42	20/03/92	36.30		76.30	150	90	82	145	85	84	84			
	541	Reboxetine	Female	Screen	02/03/92	36.10	14		125	85	60	140	90	74	

2041

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9550082

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
7/05	541	Reboxetine	Female	Day 0	17/03/92	36.40		74.30	130	80	64	135	85	78
				Day 7	24/03/92	36.20		74.10	140	80	62	140	85	72
				Day 14	31/03/92	36.10		74.50	130	75	68	140	85	76
				Day 21	07/04/92	36.50		74.30	135	80	60	140	90	73
				Day 28	14/04/92	36.50		74.60	140	90	71	140	85	79
				Day 35	21/04/92	36.00		74.50	140	80	63	135	85	74
542	542	Imipramine	Male	Day 42	28/04/92	36.00		74.40	130	75	60	130	80	68
				Screen	02/03/92	36.80	17							
				Day 0	17/03/92	36.70		83.70	110	70	87	110	75	91
				Day 7	24/03/92	36.70		83.20	115	75	84	110	80	84
				Day 14	31/03/92	36.70		83.50	105	75	79	110	80	84
				Day 21	07/04/92	36.10		83.70	115	75	83	120	80	87
543	543	Imipramine	Male	Day 28	14/04/92	36.80		83.70	110	75	78	110	80	89
				Day 35	21/04/92	36.70		83.20	110	70	80	125	75	87
				Day 42	28/04/92	36.60		83.90	120	70	80	115	80	89
				Screen	03/03/92	36.10	14							
				Day 0	18/03/92	36.10		98.40	125	85	64	120	85	68
				Day 7	25/03/92	36.20		98.30	115	75	62	120	80	65
544	544	Placebo	Female	Day 14	01/04/92	36.40		98.78	110	70	60	115	80	62
				Day 21	08/04/92	36.40		98.30	110	75	60	115	80	66
				Day 28	15/04/92	36.20		99.00	125	70	66	110	80	73
				Day 35	22/04/92	36.40		99.00	105	80	68	105	75	74
				Day 42	29/04/92	36.40		98.70	110	85	60	105	90	67
				Screen	04/03/92	36.40	17							
545	545	Placebo	Male	Day 0	05/03/92	36.90		77.10	120	65	82	125	80	76
				Day 7	12/03/92	36.50		76.90	120	75	78	125	80	79
				Day 14	19/03/92	36.70		76.00	115	80	74	125	85	81
				Day 21	26/03/92	36.50		76.10	120	80	76	115	85	82
				Day 28	02/04/92	36.40		75.90	120	75	70	110	80	74
				Day 35	09/04/92	36.40		75.60	115	80	64	110	80	71
545	545	Placebo	Male	Day 42	05/05/92	36.20		75.80	125	75	70	120	75	78
				Screen	05/03/92	36.90	18							
				Day 0	12/03/92	36.50		74.90	130	60	66	130	80	64
				Day 7	19/03/92	36.70		74.70	130	70	62	135	70	68
				Day 14	26/03/92	36.50		74.70	125	70	64	140	80	76
				Day 21	02/04/92	36.40		74.30	120	75	61	130	75	66
545	545	Placebo	Male	Day 28	09/04/92	36.50		74.80	130	80	64	150	85	70
				Day 35	16/04/92	36.40		74.60	130	80	60	150	85	69
				Day 42	23/04/92	36.20		74.70	125	80	61	150	80	64

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43

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Lying Heart Rate (beats/min)	Standing Heart Rate (beats/min)		
7/05	546	Reboxetine	Female	Screen	10/03/92	36.00	14	73.20	110	70	72	115	75	78
				Day 0	25/03/92	36.10		73.50	110	70	80	110	75	84
				Day 7	01/04/92	36.30		73.20	115	70	76	110	75	85
				Day 14	08/04/92	36.00		73.20	110	70	76	115	75	81
				Day 21	15/04/92	36.00		73.50	115	80	76	120	75	70
				Day 28	22/04/92	36.40		73.20	110	75	72	105	80	79
Day 35	29/04/92	36.00		73.20	110	70	76	110	75	84				
Day 42	06/05/92	36.20		73.20	110	70	76	110	75	84				
7/07	529	Placebo	Female	Screen	17/02/92	36.60	12	75.00	125	80	60	130	85	72
				Day 0	18/02/92	36.80		75.00	110	80	66	120	70	72
				Day 7	25/02/92	36.70		75.00	135	75	66	135	80	72
				Day 14	03/03/92	36.80		75.00	130	75	66	135	80	72
				Day 21	10/03/92	36.80		75.00	120	80	66	130	70	78
				Day 28	17/03/92	36.90		75.00	110	70	66	105	75	72
Day 35	24/03/92	36.80		75.00	100	65	66	95	70	72				
Day 42	31/03/92	36.90		75.00	100	60	70	95	65	76				
530		Imipramine	Female	Screen	17/02/92	36.70	13	75.00	145	90	90	140	90	108
				Day 0	20/02/92	36.80		74.00	160	90	82	145	80	90
				Day 7	27/02/92	36.80		74.00	130	85	78	140	80	84
				Day 14	05/03/92	36.90		74.00	140	80	78	145	85	84
531		Reboxetine	Female	Screen	18/02/92	36.70	11	85.00	160	100	78	165	105	72
				Day 0	24/02/92	36.80		85.00	150	95	66	160	90	72
				Day 7	02/03/92	36.80		85.00	140	90	66	150	85	72
				Day 14	09/03/92	36.70		85.00	160	90	68	150	85	72
				Day 21	16/03/92	36.80		85.00	160	90	72	150	85	76
				Day 28	23/03/92	36.80		85.00	140	85	66	150	90	72
Day 35	30/03/92	36.70		85.00	140	80	66	145	85	72				
Day 42	06/04/92	36.80		85.00	186	110	90	144	86	93				
532		Imipramine	Female	Screen	23/04/92	36.80	12	58.00	140	90	95	145	95	117
				Day 0	27/04/92	34.70		58.00	137	77	112	137	96	128
				Day 7	04/05/92	36.80		58.00	130	72	98	135	76	110
				Day 14	11/05/92	36.80		58.00	128	85	107	121	78	112
				Day 21	18/05/92	36.80		58.00	135	74	91	158	100	102
				Day 28	25/05/92	36.80		58.00	115	70	85	117	107	107
Day 35	01/06/92	36.80		58.00	110	68	85	109	72	98				
Day 42	09/06/92	36.70		58.00	96	66	97	118	78	111				
533		Reboxetine	Male	Screen	27/04/92	36.70	14	85.00	188	85	76	142	95	98
				Day 0	04/05/92	36.80		85.00	125	76	88	138	93	111
				Day 7	11/05/92	36.80		85.00	117	78	83	132	92	102

2043

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44

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
7/07	533	Reboxetine	Male	Day 14	18/05/92	36.80		85.00	116	73	87	126	99	112
				Day 21	25/05/92	36.90		85.00	131	77	86	126	90	117
				Day 28	01/06/92	36.80		85.00	122	74	93	122	92	113
				Day 35	08/06/92	36.80		85.00	130	89	87	138	106	116
				Day 42	15/06/92	36.80		85.00	123	81	90	139	102	125
534		Placebo	Female	Screen	12/05/92	36.60	12							
				Day 0	15/05/92	36.80		66.00	129	78	57	125	86	93
				Day 7	22/05/92	36.70		66.00	117	72	78	120	78	48
				Day 14	29/05/92	36.70		66.00	116	76	72	113	74	72
				Day 21	05/06/92	36.70		66.00	124	73	69	117	74	83
				Day 28	12/06/92	36.80		66.00	117	78	59	124	86	77
				Day 35	19/06/92	36.70		69.00	114	74	61	118	71	71
				Day 42	26/06/92	36.60		69.00	116	74	60	120	76	72
8	211	Reboxetine	Female	Screen	07/05/91	36.60	15							
				Day 0	13/05/91	36.50		65.00	120	85	76	120	85	76
				Day 7	20/05/91	36.60		65.00	120	80	74	120	80	74
				Day 14	27/05/91	36.70		65.00	130	80	72	125	80	74
212		Placebo	Female	Screen	10/09/91	36.70	15							
				Day 0	14/09/91	36.60		76.50	130	80	72	125	80	74
				Day 7	21/09/91	36.50		76.50	130	80	74	125	80	76
				Day 14	28/09/91	36.50		76.50	130	80	74	130	80	74
				Day 21	05/10/91	36.70		76.50	130	80	74	130	80	74
				Day 28	12/10/91	36.70		76.50	130	85	74	130	80	74
				Day 35	19/10/91	36.60		76.50	135	85	76	130	85	76
				Day 42	26/10/91	36.50		76.50	135	85	74	130	85	74
213		Imipramine	Male	Screen	18/11/91	36.60	16							
				Day 0	22/11/91	36.60		79.00	125	80	64	125	80	64
214		Reboxetine	Female	Screen	19/11/91	36.80	16							
				Day 0	23/11/91	36.50		72.00	135	90	72	135	90	72
				Day 7	30/11/91	36.50		72.00	120	85	72	120	85	72
				Day 14	07/12/91	36.60		72.00	125	85	70	120	85	72
				Day 21	14/12/91	36.60		72.00	120	85	74	120	85	74
				Day 28	21/12/91	36.70		72.00	125	85	74	125	85	74
Day 35	28/12/91	36.50		72.00	125	85	74	125	85	74				
215		Placebo	Female	Screen	14/02/92	36.40	15							
				Day 0	18/02/92	36.40		44.00	120	80	64	120	80	64
				Day 7	25/02/92	36.60		48.50	115	80	70	115	80	70

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2044

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45

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Height (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	Standing S.B.P. (mmHg)		
B	215	Placobo	Female	Day 14	03/03/92	36.80		48.20	110	75	70	110	75	70
				Day 21	10/03/92	36.40		49.00	125	80	70	125	80	70
				Day 28	17/03/92	36.60		48.00	120	80	72	120	80	72
				Day 35	24/03/92	36.50		48.00	120	80	70	120	80	70
		Day 42	31/03/92	36.60		48.00	120	80	72	120	75	72		
	216	Imipramine	Male	Screen	23/03/92	36.40	16		130	80	80	130	80	80
				Day 0	27/03/92	36.40		92.00	130	85	80	130	85	80
				Day 7	03/04/92	36.40		92.00	125	80	80	125	85	80
				Day 14	10/04/92	36.50		92.50	120	85	78	120	85	78
		Day 21	17/04/92	36.50		92.50	125	85	76	125	85	76		
		Day 28	24/04/92	36.50		92.50	130	85	76	130	85	76		
		Day 35	01/05/92	36.50		92.50	130	90	84	130	80	84		
		Day 42	08/05/92	36.50		92.50	135	80	78	135	80	78		
204	217	Reboxetine	Female	Screen	23/03/92	36.60	16		120	80	82	120	80	82
				Day 0	30/03/92	36.50		62.80	120	80	80	120	80	80
				Day 7	06/04/92	36.60		62.50	120	80	82	115	80	82
				Day 14	13/04/92	36.50		62.50	125	80	84	120	80	84
		Day 21	20/04/92	36.60		62.80	120	80	80	120	80	80		
		Day 28	27/04/92	36.60		63.00	125	80	82	125	80	82		
		Day 35	04/05/92	36.50		63.00	125	80	82	125	80	82		
		Day 42	11/05/92	36.70		63.00	125	75	84	125	75	84		
	218	Reboxetine	Female	Screen	01/04/92	36.60	16		155	90	72	155	90	72
				Day 0	09/04/92	36.60		66.00	155	90	72	150	85	74
				Day 7	16/04/92	36.60		66.00	150	90	74	150	90	74
				Day 14	23/04/92	36.50		66.00	145	90	76	145	90	76
		Day 21	30/04/92	36.60		66.30	140	90	76	140	90	76		
		Day 28	07/05/92	36.50		66.30	140	90	76	140	90	76		
		Day 35	14/05/92	36.60		66.30	140	90	74	140	90	74		
		Day 42	21/05/92	36.60		66.40	140	90	78	140	90	78		
	219	Placobo	Female	Screen	03/04/92	36.50	16		110	80	70	110	80	70
				Day 0	11/04/92	36.50		52.00	110	80	72	110	80	72
				Day 7	18/04/92	36.60		52.00	110	80	70	110	80	70
				Day 14	24/04/92	36.60		52.00	115	80	70	115	80	70
		Day 21	02/05/92	36.50		52.00	115	75	70	115	75			
	220	Imipramine	Female	Screen	21/04/92	36.50	16		145	80	84	145	80	84
				Day 0	27/04/92	36.60		56.50	120	80	82	120	80	82
				Day 7	04/05/92	36.50		56.60	125	85	84	125	85	84
				Day 14	11/05/92	36.60		56.80	115	80	82	115	80	82
		Day 21	18/05/92	36.60		56.80	115	80	82	115	80			

9550082

46

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PIARNACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 20.0
 VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing (beats/min)		
B	220	Imipramine	Female	Day 28	25/05/92	36.60		56.80	125	80	82	120	75	84
				Day 35	01/06/92	36.60		56.70	130	80	80	125	75	84
				Day 42	08/06/92	36.50		56.70	130	80	78	130	75	78
	221	Imipramine	Male	Screen	24/04/92	36.60	16		130	80	78	130	80	78
				Day 0	28/04/92	36.60		77.00	130	80	78	130	80	78
				Day 7	05/05/92	36.50		77.00	130	85	80	130	85	80
				Day 14	12/05/92	36.60		77.00	135	85	82	135	85	82
				Day 21	19/05/92	36.50		77.00	135	85	78	130	85	80
				Day 28	26/05/92	36.50		77.00	130	80	78	130	80	78
	222	Placebo	Female	Screen	20/04/92	36.60	16		120	70	64	120	70	64
				Day 0	28/04/92	36.50		66.00	120	75	62	120	75	62
				Day 7	05/05/92	36.60		66.00	125	80	64	125	80	64
				Day 14	12/05/92	36.50		66.00	130	80	64	130	80	64
				Day 21	19/05/92	36.50		66.20	125	80	62	125	80	62
				Day 28	26/05/92	36.50		66.20	130	80	60	125	80	62
	223	Imipramine	Female	Screen	04/05/92	36.40	16		110	80	82	110	80	82
				Day 0	11/05/92	36.40		54.00	125	75	80	125	75	80
				Day 7	18/05/92	36.60		54.00	120	80	78	120	80	78
				Day 14	25/05/92	36.60		54.00	120	80	78	120	80	78
				Day 21	01/06/92	36.50		54.00	115	80	70	115	80	70
				Day 28	08/06/92	36.60		54.20	125	80	80	125	80	80
	224	Placebo	Female	Screen	27/08/92	36.70	16		120	75	82	120	75	82
				Day 0	07/09/92	36.60		54.20	125	85	72	120	80	75
				Day 7	14/09/92	36.60		56.00	115	80	82	115	80	80
				Day 14	21/09/92	36.50		56.00	110	80	82	110	80	82
				Day 21	28/09/92	36.50		56.00	115	85	80	115	85	80
				Day 28	05/10/92	36.60		54.50	115	85	82	115	85	82
	225	Placebo	Male	Screen	05/09/92	36.60	16		120	80	78	120	80	78
				Day 0	11/09/92	36.50		68.00	120	80	80	120	80	80
				Day 7	18/09/92	36.60		68.00	120	85	82	120	85	82
				Day 14	25/09/92	36.50		68.00	115	85	80	115	85	80
				Day 21	02/10/92	36.50		68.00	115	85	80	115	85	80
				Day 28	09/10/92	36.50		68.00	115	85	80	115	85	80

2046

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

47

9550082

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	Standing D.B.P. (mmHg)		
8	225	Placebo	Male	Day 23	09/10/92	36.60		68.00	115	80	82	110	80	82
				Day 35	16/10/92	36.50		68.00	115	85	82	115	80	82
				Day 42	23/10/92	36.50		68.00	110	85	82	110	80	84
	226	Reboxetine	Male	Screen	21/09/92	36.50	16		140	90	78	140	90	78
				Day 0	23/09/92	36.60		62.00	140	90	78	140	90	78
				Day 7	30/09/92	36.50		62.00	140	90	80	140	85	80
				Day 14	07/10/92	36.60		62.00	140	85	82	140	85	82
				Day 21	14/10/92	36.60		62.00	135	80	80	135	80	80
				Day 28	21/10/92	36.50		62.00	135	85	82	130	85	84
	227	Reboxetine	Male	Day 35	28/10/92	36.50		62.00	135	80	82	135	80	82
				Day 42	04/11/92	36.40		62.00	135	85	72	135	80	74
				Screen	18/09/92	36.50	16		160	90	86	160	90	86
Day 0				25/09/92	36.60		70.00	160	90	86	160	90	84	
Day 7				02/10/92	36.50		70.00	160	90	86	160	90	86	
Day 14				09/10/92	36.50		70.00	155	90	84	155	90	84	
228	Imipramine	Male	Day 21	16/10/92	36.50		70.00	160	90	84	160	85	84	
			Day 28	23/10/92	36.70		70.00	150	90	82	150	90	82	
			Day 35	30/10/92	36.60		70.00	150	90	82	150	85	84	
			Day 42	06/11/92	36.60		70.00	155	90	82	150	90	82	
			Screen	18/09/92	36.50	16		125	85	82	125	85	82	
			Day 0	25/09/92	36.60		74.00	120	80	82	120	80	82	
229	Imipramine	Female	Day 7	03/10/92	36.60		74.00	115	80	82	115	80	82	
			Screen	24/09/92	36.50	16		135	85	82	135	85	82	
			Day 0	30/09/92	36.70		66.00	140	85	82	135	85	82	
			Day 7	07/10/92	36.30		66.00	135	80	78	135	80	78	
			Day 14	14/10/92	36.50		66.00	135	85	80	130	85	82	
			Day 21	21/10/92	36.60		66.50	125	80	82	125	75	82	
230	Reboxetine	Female	Day 28	28/10/92	36.70		66.50	130	80	78	130	80	78	
			Day 35	04/11/92	36.60		66.50	125	80	80	125	80	80	
			Day 42	11/11/92	36.50		66.50	130	85	82	130	85	82	
			Screen	24/09/92	36.60	16		125	80	74	120	80	76	
			Day 0	28/09/92	36.50		56.00	115	80	74	115	80	74	
			Day 7	05/10/92	36.50		56.00	120	85	70	120	85	70	
2047	Reboxetine	Female	Day 14	32/10/92	36.70		56.00	115	80	72	115	80	72	
			Day 21	19/10/92	36.70		56.00	120	75	70	120	75	70	
			Day 28	26/10/92	36.50		56.00	125	80	72	125	80	72	
			Day 35	02/11/92	36.60		56.00	125	85	72	120	85	74	
			Day 42	09/11/92	36.70		56.00	125	85	72	125	85	72	
			Day 42	09/11/92	36.60		56.00	125	85	72	125	85	72	

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing			
8	231	Imipramine	Male	Screen	25/09/92	36.60	16	88.00	145	85	76	145	85	76	
				Day 0	30/09/92	36.50		88.00	140	85	72	140	80	80	74
				Day 7	07/10/92	36.40		88.00	140	85	72	140	85	85	72
				Day 14	14/10/92	36.50		88.00	135	85	68	135	85	85	68
				Day 21	21/10/92	36.60		88.00	140	80	70	135	80	70	70
	Day 28	28/10/92	36.50		88.00	135	85	72	135	85	72	72			
	Day 35	04/11/92	36.50		88.00	135	85	70	135	80	72	72			
	Day 42	11/11/92	36.70		88.00	140	85	72	135	85	72	72			
	232	Reboxetine	Male	Screen	25/09/92	36.50	16	76.00	130	85	88	125	85	88	
				Day 0	02/10/92	36.60		76.00	136	85	86	125	85	86	
Day 7				09/10/92	36.60		76.00	136	85	86	130	85	86		
Day 14				16/10/92	36.70		76.00	130	85	88	130	85	88		
Day 21				23/10/92	36.70		76.00	129	80	82	120	80	82		
Day 28		30/10/92	36.50		76.00	125	85	86	125	85	86				
Day 35		06/11/92	36.50		76.00	130	90	86	130	85	86				
Day 42		13/11/92	36.70		76.00	125	85	82	125	85	82				
233		Placebo	Female	Screen	28/09/92	36.40	16	70.00	125	80	84	125	80	84	
				Day 0	07/10/92	36.50		70.00	120	85	82	125	85	82	
	Day 7			14/10/92	36.50		70.00	120	85	84	120	85	84		
	Day 14			21/10/92	36.70		69.00	130	90	86	125	85	82		
	Day 21			28/10/92	36.70		69.00	130	85	84	130	85	84		
	Day 28	04/11/92	36.60		69.00	130	85	84	130	85	84				
	Day 35	11/11/92	36.60		69.50	130	85	84	125	85	86				
	Day 42	18/11/92	36.80		70.00	120	80	78	120	80	80				
	234	Placebo	Female	Screen	30/09/92	36.40	16	62.00	150	82	70	150	85	70	
				Day 0	07/10/92	36.50		62.00	155	85	78	155	85	78	
Day 7				14/10/92	36.60		62.00	155	85	76	155	85	76		
Day 14				21/10/92	36.50		62.00	150	85	74	150	85	74		
Day 21				28/10/92	36.70		62.00	165	85	72	165	80	74		
Day 28		04/11/92	36.50		62.00	140	80	72	140	80	72				
Day 35		11/11/92	36.60		62.00	140	85	74	140	80	74				
Day 42		18/11/92	36.70		62.00	140	80	72	135	80	72				
8/A		235	Placebo	Female	Screen	18/09/92	36.00	20	75.00	145	65	70	140	85	72
					Day 0	14/10/92	36.20		75.00	140	80	72	140	85	70
	Day 7				20/10/92	36.00		75.00	140	80	70	135	80	72	
	Day 14				27/10/92	36.20		75.00	140	75	70	135	75	71	
	Day 21				04/11/92	36.40		75.00	145	75	70	130	75	69	
	Day 28	10/11/92	36.30		74.00	135	80	68	135	80	69				
	Day 35	17/11/92	36.30		74.00	135	80	70	135	80	72				

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2048

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing		
8/A	235	Placebo	Female	Day 42	24/11/92	36.30		74.00	130	75	70	130	70	70
	236	Placebo	Female	Screen	18/09/92	36.40			120	75	80	125	80	71
				Day 0	14/10/92	36.80	19	85.00	135	80	74	140	80	73
				Day 7	20/10/92	36.60		84.50	130	80	77	140	80	77
				Day 14	27/10/92	36.00		84.00	125	80	76	130	80	75
				Day 21	04/11/92	36.00		83.50	130	70	70	130	75	68
				Day 28	10/11/92	36.50		85.00	130	80	70	135	85	72
				Day 35	17/11/92	36.40		84.50	130	75	70	130	80	72
				Day 42	24/11/92	36.20		83.00	130	70	70	125	70	72
	237	Reboxetine	Female	Screen	18/09/92	36.00	21		130	80	82	130	80	84
				Day 0	14/10/92	36.10		62.00	130	80	84	130	80	84
				Day 7	20/10/92	36.40		62.00	125	80	82	130	80	82
				Day 14	27/10/92	36.40		62.00	125	80	82	130	80	80
				Day 21	03/11/92	36.00		62.00	130	75	68	130	80	68
				Day 28	10/11/92	36.50		62.00	130	80	77	130	85	79
				Day 35	18/11/92	36.10		62.00	130	70	72	135	70	72
				Day 42	24/11/92	36.20		62.00	130	75	68	125	70	68
	238	Reboxetine	Female	Screen	18/09/92	36.30	22		145	85	80	140	85	80
				Day 0	14/10/92	36.20		60.00	145	85	80	140	85	80
				Day 7	20/10/92	36.00		59.00	135	85	82	135	80	80
				Day 14	27/10/92	36.30		59.00	135	80	80	130	75	82
				Day 21	04/11/92	36.40		60.00	140	75	70	140	70	72
				Day 28	10/11/92	36.40		59.00	135	80	68	135	80	68
				Day 35	17/11/92	36.10		59.00	130	80	67	130	75	69
				Day 42	24/11/92	36.10		59.00	130	75	65	130	70	67
	239	Imipramine	Female	Screen	22/09/92	36.30	20		145	90	68	140	85	68
				Day 0	16/10/92	36.20		61.50	145	85	70	145	80	70
				Day 7	22/10/92	36.30		62.00	140	75	70	140	85	72
				Day 14	29/10/92	36.30		62.00	140	80	70	145	80	70
				Day 21	05/11/92	36.20		62.00	140	80	68	140	75	68
				Day 28	12/11/92	36.00		61.50	130	85	68	135	85	68
				Day 35	19/11/92	36.60		61.50	130	70	70	130	75	70
				Day 42	26/11/92	36.40		62.00	135	80	78	135	75	76
	240	Imipramine	Female	Screen	22/09/92	36.00	18		120	80	84	120	78	84
				Day 0	16/10/92	36.20		68.00	135	80	78	135	75	78
				Day 7	22/10/92	36.40		68.00	125	80	76	125	80	76
				Day 14	29/10/92	36.30		68.50	130	85	74	130	80	74
				Day 21	05/11/92	36.00		68.00	130	75	78	130	80	78
				Day 28	12/11/92	36.30		68.50	130	80	72	130	80	72

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50

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Height (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing D.B.P. (mmHg)		
B/A	240	Imipramine	Female	Day 35 Day 42	19/11/92 26/11/92	36.00 36.20		68.00 68.00	125 125	70 70	70 70	120 125	70 75	70 70
	553	Placebo	Female	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42	22/09/92 16/10/92 22/10/92 29/10/92 05/11/92 12/11/92 19/11/92 26/11/92	36.00 36.60 36.60 36.20 36.40 36.30 36.30	18	68.00 68.00 68.00 68.00 68.00 68.00 68.00	115 145 140 130 140 140 130	70 75 80 70 75 72 70	80 78 80 70 80 72 70	115 140 140 130 140 140 130	70 80 80 70 75 75 70	80 78 80 80 80 72 68
	554	Reboxetine	Male	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42	22/09/92 16/10/92 22/10/92 29/10/92 05/11/92 12/11/92 19/11/92 26/11/92	36.00 36.30 36.40 36.60 36.30 36.40 36.20	16	64.00 64.00 64.00 64.00 64.00 64.00 64.00	145 150 145 145 150 145 150	80 85 80 75 80 62 80	62 64 62 64 64 62 60	140 150 140 140 140 140 145	80 80 75 80 80 75 80	62 64 62 64 64 62 60
	555	Reboxetine	Female	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42	22/09/92 16/10/92 22/10/92 29/10/92 05/11/92 12/11/92 19/11/92 26/11/92	36.60 36.10 36.70 36.60 36.30 36.40 36.20	19	57.00 57.50 56.50 58.00 56.00 56.40 56.20	145 140 145 140 135 140 135	85 80 85 80 75 70 70	71 72 74 72 68 70 68	140 140 145 130 140 140 130	85 80 80 80 75 70 75	72 70 74 72 68 70 68
	556	Imipramine	Male	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42	22/09/92 16/10/92 22/10/92 29/10/92 05/11/92 12/11/92 19/11/92 26/11/92	36.40 36.30 36.20 36.20 36.30 36.20 36.40	19	64.00 64.00 64.00 64.00 64.00 64.00 64.00	120 120 120 125 120 130 130	60 60 80 65 82 80 70	60 60 80 60 84 82 82	120 120 120 125 120 130 130	60 60 70 60 125 120 130	82 80 80 80 82 82 82
9	241	Placebo	Female	Screen Day 0 Day 7 Day 14	04/02/91 07/02/91 14/02/91 18/02/91	36.00 36.20 36.90	18	58.00 58.00	120 115 140	80 75 90	80 83 82	120 110 115	80 70 75	83 87 85

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2050

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	Heart Rate (beats/min) standing		
9	242	Reboxetine	Female	Screen	12/02/91	36.00	20	50.00	115	80	90	115	80	90
				Day 0	18/02/91	36.20		50.00	140	80	84	135	80	88
				Day 7	25/02/91	36.30		50.00	130	80	82	130	80	84
				Day 14	04/03/91	36.40		50.00	120	80	80	120	80	80
	243	Reboxetine	Female	Screen	15/02/91	36.20	13	67.50	120	80	70	120	80	70
				Day 0	20/02/91	36.10		67.30	130	90	74	120	80	74
				Day 7	26/02/91	36.10		67.30	130	90	70	130	90	70
				Day 14	06/03/91	36.40		67.20	150	100	75	150	100	75
2001	244	Imipramine	Female	Screen	14/02/91	36.00	15	72.00	130	80	80	130	80	80
				Day 0	19/02/91	36.40		72.00	130	80	80	130	80	80
				Day 7	26/02/91	36.80		72.00	130	80	80	130	80	80
				Day 14	05/03/91	36.30		71.50	130	80	80	130	80	80
				Day 21	12/03/91	36.30		72.00	130	80	82	130	80	80
				Day 28	13/03/91	36.40		72.00	120	70	85	120	70	85
245	245	Imipramine	Female	Screen	18/02/91	36.30	12	60.00	110	70	68	110	70	70
				Day 0	22/02/91	36.20		60.00	120	70	68	120	70	68
				Day 7	01/03/91	36.10		60.20	110	70	70	110	70	70
				Day 14	08/03/91	36.20		60.50	110	80	66	110	80	66
				Day 21	15/03/91	36.30		61.00	110	70	72	110	70	72
				Day 28	22/03/91	36.20		61.00	110	70	66	110	70	66
246	246	Placebo	Female	Screen	13/02/91	36.00	18	58.00	130	80	80	125	75	85
				Day 0	22/02/91	36.40		63.00	120	80	90	120	80	90
				Day 7	01/03/91	36.20		60.00	160	85	70	160	85	70
				Day 14	08/03/91	36.40		58.00	130	80	70	130	80	70
				Day 21	15/03/91	36.20		58.00	110	60	60	100	60	60
				Day 28	18/03/91	36.90		57.70	130	100	80	130	95	80
247	247	Placebo	Female	Screen	20/02/91	36.20	14	60.00	105	70	70	105	70	70
				Day 0	25/02/91	36.20		60.00	105	70	68	105	70	68
				Day 7	04/03/91	36.30		60.00	115	70	74	115	70	70
				Day 14	11/03/91	36.10		60.00	110	65	70	110	65	72
				Day 21	18/03/91	36.10		60.00	90	60	90	90	60	90
				Day 28	26/03/91	36.20		60.00	95	75	78	95	75	78

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9550082

52

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									Lying			Standing			
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	
9	248	Placebo	Male	Screen	04/03/91	36.30	13	81.20	120	75	74	120	75	74	
				Day 0	08/03/91	36.20		80.90	110	70	76	110	70	78	
				Day 7	15/03/91	36.20		81.10	120	70	74	100	70	74	
					Day 14	22/03/91	36.30			120	70	78	120	70	78
	249	Reboxetine	Female	Screen	04/03/91	36.00	18	72.00	120	70	72	120	70	70	
				Day 0	04/03/91	36.00			110	60	72	110	60	72	
	250	Imipramine	Female	Screen	07/03/91	36.00	15	54.50	140	100	74	135	98	76	
				Day 0	12/03/91	36.40		54.00	130	90	83	130	90	83	
				Day 7	19/03/91	36.30		54.00	80	80	80	130	80	80	
Day 14				26/03/91	36.20		54.00	80	80	82	130	80	82		
Day 21				02/04/91	36.30		54.50	90	85	130	90	90	83		
Day 28				08/04/91	36.20		54.50	90	80	135	90	90	80		
251	Imipramine	Female	Screen	18/03/91	36.40	12	61.00	120	80	68	120	80	68		
			Day 0	20/03/91	36.20		61.00	125	80	76	125	80	76		
			Day 7	27/03/91	37.20		61.40	120	80	72	120	80	72		
			Day 14	03/04/91	36.30		61.00	120	80	76	120	80	76		
			Day 21	10/04/91	36.10		61.00	125	80	80	125	80	80		
252	Reboxetine	Female	Screen	28/03/91	36.40	14	116.00	130	90	82	130	90	82		
			Day 0	02/04/91	36.30		116.00	140	80	70	140	80	70		
			Day 7	09/04/91	36.30		115.00	130	90	78	130	90	78		
			Day 14	16/04/91	36.10		115.00	140	70	74	140	70	74		
				Day 21	20/04/91	36.10			150	90	72	150	90	72	
253	Reboxetine	Female	Screen	29/03/91	36.00	15	67.50	115	70	80	115	70	80		
			Day 0	02/04/91	36.40		67.50	110	80	80	110	75	80		
			Day 7	08/04/91	36.20		67.50	115	80	80	110	80	80		
254	Imipramine	Female	Screen	05/04/91	36.10	13	71.00	125	80	78	125	80	78		
			Day 0	09/04/91	36.10		71.00	130	80	72	130	80	72		
			Day 7	16/04/91	36.30		71.00	140	80	70	140	80	70		
			Day 14	17/04/91	36.20		71.00	140	80	72	140	80	72		
255	Reboxetine	Female	Screen	08/05/91	36.00	18	76.00	130	70	80	130	70	80		
			Day 0	13/05/91	36.20		76.00	110	75	80	105	75	80		
			Day 7	20/05/91	36.40		76.00	110	70	83	110	70	85		
			Day 14	27/05/91	36.40		76.00	115	65	80	110	65	84		
			Day 21	03/06/91	36.40		76.00	110	70	80	110	70	88		
Day 28	06/06/91	36.20		76.30	110	70	80	110	70	84					

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

53

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing (beats/min)			
9	256	Imipramine	Female	Screen	23/05/91	36.00	15	56.20	130	90	80	130	90	83	
				Day 0	27/05/91	36.50			120	80	120	80			
				Day 7	03/06/91	36.90			100	70	75	110	70	70	75
				Day 14	10/06/91	36.40			57.00	90	80	120	90	80	85
				Day 21	17/06/91	36.40			57.00	130	90	80	130	90	80
11	257	Placebo	Male	Screen	21/06/91	36.20	12	57.00	100	60	83	100	60	85	
				Day 0	25/06/91	36.10			105	60	80	100	60	80	
				Day 7	01/07/91	36.10			125	80	74	125	80	74	74
				Screen	26/06/91	36.30	13	48.50	100	70	80	100	70	80	80
				Day 0	01/07/91	36.10			100	70	70	100	70	70	70
11	258	Placebo	Male	Screen	26/06/91	36.30	13	48.50	100	70	80	100	70	80	
				Day 0	01/07/91	36.10			100	70	70	100	70	70	70
				Day 7	08/07/91	36.30			105	70	70	105	70	70	70
				Day 14	10/07/91	36.40			100	70	78	100	70	70	78
				Screen	25/07/91	37.00	16	74.00	125	85	80	120	85	80	76
11	319	Placebo	Male	Day 0	01/08/91	37.00			120	70	76	120	75	72	
				Day 7	08/08/91	37.00			130	75	72	125	75	72	
				Day 14	15/08/91	37.00			140	80	72	130	80	72	
				Day 21	22/08/91	37.00			130	85	72	125	80	72	
				Day 28	29/08/91	37.00			130	80	72	130	80	72	
11	320	Imipramine	Male	Screen	08/08/91	37.00	14	75.00	130	80	72	125	80	72	
				Day 0	15/08/91	37.00			175	80	72	125	80	72	
				Day 7	22/08/91	37.00			110	80	76	110	75	76	
				Day 14	29/08/91	37.00			120	80	76	115	80	76	
				Day 21	05/09/91	37.00			130	90	72	120	80	72	
11	321	Placebo	Male	Screen	27/08/91	37.00	12	65.00	130	85	76	130	85	76	
				Day 0	05/09/91	37.00			130	85	76	130	85	76	
				Day 7	12/09/91	37.00			100	80	76	130	95	76	
				Day 14	19/09/91	37.00			130	85	76	130	85	76	
				Day 21	26/09/91	37.00			67.00	140	72	140	95	72	
11	320	Imipramine	Male	Day 28	03/10/91	37.00			130	90	72	130	90	72	
				Day 35	10/10/91	37.00			67.00	130	90	72	130	90	72

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									Lying			Standing		
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
11	321	Placebo	Male	Day 42	17/10/91	37.00		67.00	140	100	72	130	90	72
	322	Reboxetine	Female	Screen	19/09/91	37.00		73.00	130	80	76	134	80	76
				Day 0	26/09/91	37.00	14	80	130	85	76	130	80	76
				Day 7	03/10/91	37.00		73.00	120	80	72	120	75	72
				Day 14	10/10/91	37.00		73.00	130	90	72	130	80	72
				Day 21	19/10/91	37.00		73.00	130	85	72	120	80	72
				Day 28	24/10/91	37.00		72.50	130	80	72	110	75	72
				Day 35	31/10/91	37.00		72.00	120	80	72	120	80	72
				Day 42	07/11/91	37.00		75.00	120	80	72	120	80	72
	323	Reboxetine	Male	Screen	05/11/91	37.00		65.00	130	80	72	130	80	72
				Day 0	14/11/91	37.00	14	63.00	120	80	72	130	80	72
				Day 7	21/11/91	37.00		64.00	130	80	72	125	80	72
				Day 14	28/11/91	37.00		64.00	130	75	72	130	70	72
				Day 21	05/12/91	37.00		64.50	110	90	76	130	85	72
				Day 28	12/12/91	37.00		65.00	130	80	72	130	80	72
				Day 35	19/12/91	37.00		65.00	130	80	72	130	80	72
				Day 42	27/12/91	37.00		65.00	130	80	72	130	80	72
	324	Imipramine	Male	Screen	29/11/91	37.00		76.00	130	85	72	130	80	72
				Day 0	05/12/91	37.00	14	75.00	125	90	76	120	85	76
				Day 7	12/12/91	37.00		75.00	120	90	76	120	85	72
				Day 14	19/12/91	37.00		75.00	120	85	76	120	85	72
				Day 21	27/12/91	37.00		75.00	130	90	72	130	90	72
				Day 28	02/01/92	37.00		75.00	130	90	72	130	85	72
				Day 35	09/01/92	37.00		75.00	130	90	76	130	85	72
				Day 42	16/01/92	37.00		75.00	120	90	76	120	90	76
	325	Reboxetine	Male	Screen	06/12/91	37.00		83.00	110	75	72	110	72	72
				Day 0	12/12/91	37.00	14	83.00	110	75	72	110	72	72
				Day 7	19/12/91	37.00		83.00	113	75	72	115	75	72
				Day 14	27/12/91	37.00		83.00	115	75	72	115	75	72
				Day 21	02/01/92	37.00		85.00	120	80	72	120	72	72
				Day 28	09/01/92	37.00		85.00	120	80	72	120	80	72
				Day 35	16/01/92	37.00		85.00	120	80	72	120	80	72
				Day 42	23/01/92	37.00		85.00	120	85	72	115	80	72
	326	Placebo	Male	Screen	14/01/92	37.00		75.00	130	105	72	130	100	72
				Day 0	16/01/92	37.00	12	75.00	130	105	72	130	100	72
				Day 7	23/01/92	37.00		75.00	140	100	72	130	100	72
				Day 14	30/01/92	37.00		76.00	140	100	72	110	100	72
				Day 21	06/02/92	37.00		76.00	150	100	72	145	100	72
				Day 28	13/02/92	37.00		76.00	130	100	72	130	100	72

2034

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Center	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									Lying			Standing		
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
11	326	Placebo	Male	Day 35	28/02/92	37.00		76.00	100	72	125	100	72	72
				Day 42	27/02/92	37.00		76.00	100	72	130	100	72	72
11	327	Imipramine	Male	Screen	23/01/92	37.00	12	64.50	70	72	120	70	72	72
				Day 0	29/01/92	37.00		64.00	70	72	115	70	72	72
				Day 7	05/02/92	37.00		64.00	80	72	120	80	72	72
11	328	Imipramine	Female	Screen	28/01/92	37.00	14	60.00	80	76	110	80	76	76
				Day 0	30/01/92	37.00		60.00	75	76	110	75	76	76
				Day 7	05/02/92	37.00		60.00	80	72	110	70	72	72
11	329	Placebo	Female	Screen	01/04/92	37.00	12	86.00	95	72	140	95	72	72
				Day 0	09/04/92	37.00		86.00	95	76	140	95	72	76
				Day 7	16/04/92	37.00		87.00	95	76	140	95	76	76
				Day 14	23/04/92	37.00		88.00	95	76	140	95	76	72
				Day 21	30/04/92	37.00		88.00	100	72	160	140	85	72
				Day 28	07/05/92	37.00		87.00	105	72	140	105	72	72
				Day 35	14/05/92	37.00		89.00	90	72	140	90	72	72
				Day 42	21/05/92	37.00		89.00	90	72	140	90	72	72
				Screen	06/04/92	37.00	14	69.00	80	76	120	80	76	76
				Day 0	09/04/92	37.00		69.00	90	76	120	80	76	76
				Day 7	16/04/92	37.00		69.00	80	72	120	80	72	72
Day 14	23/04/92	37.00		69.00	80	72	120	80	72	72				
Day 21	30/04/92	37.00		69.00	85	78	120	80	72	72				
Day 28	07/05/92	37.00		69.00	80	72	120	80	72	72				
Day 35	14/05/92	37.00		69.00	85	72	120	85	72	72				
Day 42	21/05/92	37.00		69.00	85	76	120	85	72	72				
11	331	Imipramine	Male	Screen	08/04/92	37.00	14	76.00	85	72	120	85	72	72
				Day 0	16/04/92	37.00		76.00	85	72	120	85	72	72
				Day 7	23/04/92	37.00		74.00	90	72	130	90	72	72
				Day 14	30/04/92	37.00		74.50	90	72	130	90	72	72
				Day 21	07/05/92	37.00		75.00	90	72	130	90	72	72
				Day 28	14/05/92	37.00		75.00	90	76	125	90	72	72
				Day 35	21/05/92	37.00		75.00	90	72	130	90	72	72
Day 42	28/05/92	37.00		75.00	90	72	130	90	72	72				
11	332	Reboxetine	Male	Screen	15/05/92	37.00	12	79.00	85	72	130	85	72	72
				Day 0	18/05/92	37.00		79.00	85	72	130	85	72	72
				Day 7	26/05/92	37.00		79.00	80	76	130	80	72	72
				Day 14	01/06/92	37.00		79.00	80	72	130	80	72	72
				Day 21	08/06/92	37.00		79.00	80	76	130	80	72	76

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE				
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing (beats/min)	
11	332	Reboxetine	Male	Day 28	15/06/92	37.00		79.00	125	85	72	85	72
				Day 35	22/06/92	37.00		79.00	120	80	72	120	80
	333	Placebo	Male	Screen	18/05/92	37.00	17	133.00	130	85	76	130	85
				Day 0	26/05/92	37.00		133.00	130	80	72	130	80
	334	Reboxetine	Female	Screen	24/05/92	37.00	12	43.00	110	75	68	110	75
				Day 0	28/05/92	37.00		43.00	110	75	76	110	70
	335	Placebo	Male	Screen	21/05/92	37.00	12	103.00	110	70	72	110	70
				Day 0	02/06/92	37.00		103.00	110	75	72	110	75
	336	Imipramine	Female	Screen	15/06/92	37.00	14	99.50	130	95	76	130	95
				Day 0	18/06/92	37.00		99.50	130	80	76	130	80
	337	Reboxetine	Female	Screen	16/06/92	37.00	12	64.00	110	70	72	110	70
				Day 0	02/07/92	37.00		64.00	110	70	72	110	70
	338	Imipramine	Male	Screen	14/07/92	37.00	14	75.00	120	70	76	120	70
				Day 0	23/07/92	37.00		75.00	110	70	76	110	70

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012/4/015
 Listing No.: 20.0
 VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE				
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	Standing S.B.P. (mmHg)	
12	367	Reboxetine	Female	Screen	17/12/91	37.00	20	144	80	78	136	80	92
				Day 0	20/12/91	37.50		138	84	76	134	84	74
				Day 7	27/12/91	36.70		104	70	78	90	58	80
				Day 14	03/01/92	36.80		124	86	100	100	78	90
				Day 21	10/01/92	36.00		104	70	78	80	80	78
				Day 28	16/01/92	36.30		100	50	92	90	60	88
	Day 35	23/01/92	35.40		112	70	84	90	60	90			
	Day 42	31/01/92	36.50		106	72	72	98	52	86			
	368	Placebo	Female	Screen	19/12/91	36.90	16	124	78	76	110	70	90
				Day 0	24/12/91	36.40		104	60	74	100	62	90
				Day 7	31/12/91	36.80		112	74	86	110	80	86
				Day 14	07/01/92	36.80		102	64	70	100	68	84
Day 21				14/01/92	36.70		108	72	64	110	78	72	
Day 28				21/01/92	34.70		110	64	72	110	60	80	
Day 35	28/01/92	36.40		102	70	72	98	66	74				
Day 42	04/02/92	36.70		92	60	72	98	62	70				
369	Imipramine	Female	Screen	17/04/92	36.30	24	115	89	97	113	90	90	
			Day 0	22/04/92	36.50		112	86	97	114	84	95	
			Day 7	29/04/92	36.30		112	72	84	98	70	88	
			Day 14	06/05/92	36.30		126	90	80	102	80	84	
			Day 21	13/05/92	36.40		118	76	66	102	76	71	
			Day 28	20/05/92	37.00		148	86	74	112	80	82	
370	Placebo	Male	Screen	23/04/92	36.30	24	160	94	84	140	92	92	
			Day 0	28/04/92	36.50		136	74	76	130	72	80	
			Day 7	05/05/92	36.40		126	80	70	110	72	88	
			Day 14	12/05/92	36.30		158	86	69	146	80	78	
			Day 21	19/05/92	37.00		172	86	76	114	70	82	
			Day 28	26/05/92	37.00		148	86	74	112	80	82	
371	Imipramine	Female	Screen	27/04/92	36.40	20	110	60	70	100	70	66	
			Day 0	01/05/92	36.70		100	70	58	110	74	58	
			Day 7	08/05/92	37.00		114	76	72	104	72	84	
372	Reboxetine	Male	Screen	28/05/92	36.30	24	160	110	66	120	50	68	
			Day 0	02/06/92	36.00		160	108	68	120	80	67	
			Day 7	08/06/92	36.00		142	102	66	110	80	80	
			Day 14	15/06/92	36.50		160	120	76	114	80	80	
			Day 21	22/06/92	37.00		150	100	72	120	84	67	
			Day 28	30/06/92	37.00		140	100	76	120	90	72	
Day 35	06/07/92	36.00		170	112	66	110	80	80				

9550082

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58

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE								
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	Standing Heart Rate (beats/min)					
12	372	Reboxetine	Male	Day 42	13/07/92	37.30		130.00	170	114	64	110	80	72			
				Screen	03/06/92	36.40		71.70	118	74	76	112	70	80			
	373	Reboxetine	Male	Day 0	05/06/92	36.20	16	72.00	110	72	70	70	110	70	72		
				Day 7	11/06/92	36.20		71.00	100	60	72	97	64	90			
				Day 14	18/06/92	36.40		75.50	120	74	74	104	66	86			
				Day 21	25/06/92	36.20		74.90	110	60	76	102	68	84			
				Day 28	02/07/92	36.80		74.30	104	70	62	108	68	70			
				Day 35	09/07/92	36.50		72.40	102	70	70	104	72	80			
				Day 42	16/07/92	36.50											
				Screen	03/06/92	36.00	24	71.20	106	68	72	98	56	80			
13	374	Placebo	Female	Day 0	09/06/92	37.00		72.10	102	72	70	96	70	76			
				Day 7	15/06/92	36.20		72.80	116	72	70	114	78	74			
	375	Imipramine	Male	Day 14	22/06/92	36.30		76.80	120	72	73	102	68	76			
				Day 21	30/06/92	36.20		76.30	100	68	70	110	72	68			
				Day 28	06/07/92	36.40		72.00	120	78	53	110	68	66			
				Screen	11/06/92	35.70	16	70.30	98	52	64	90	52	76			
				Day 0	15/06/92	37.00			100	70	62	90	50	74			
				14	Placebo	Male	Screen	11/04/91	37.00	20	80.00	130	70	80	125	70	82
							Day 0	12/04/91	37.00		81.00	130	80	78	125	80	84
							Day 7	19/04/91	36.80		79.20	100	80	76	95	75	80
Day 14	26/04/91	36.80					79.20	95	75	68	95	75	70				
Day 21	03/05/91	36.70					80.00	95	68	66	98	60	70				
Day 28	10/05/91	36.20					78.00	95	65	68	90	65	76				
Day 35	17/05/91	36.70					78.40	95	65	68	105	70	76				
Day 42	24/05/91	36.60															
15	14	Placebo	Male	Screen	02/07/91	37.00	18	78.00	100	75	76	105	80	82			
				Day 0	02/07/91	36.80		78.00	100	65	76	95	65	78			
	15	Imipramine	Female	Day 7	09/07/91	36.80		76.00	110	75	80	100	80	80			
				Day 14	16/07/91	37.00		76.00	95	70	70	90	75	74			
				Day 21	23/07/91	37.00		75.50	95	75	72	105	80	76			
				Day 28	30/07/91	36.80		74.50	110	80	72	110	90	72			
				Day 35	06/08/91	36.60		76.00	95	75	66	105	75	68			
				Day 42	13/08/91	36.80		76.50	120	75	78	120	80	80			
				Screen	04/07/91	36.80	18	80.00	100	70	78	100	70	86			
				Day 0	04/07/91	37.10		80.00	110	75	78	100	70	80			
Day 7	11/07/91	37.00		80.80	105	85	80	100	70	84							
Day 14	18/07/91	36.70		80.80	120	90	72	120	80	76							

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59

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE								
									Lying			Standing					
						S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)						
13	15	Imipramine	Female	Day 21	25/07/91	36.50		80.80	110	90	80	110	90	80			
				Day 28	01/08/91	36.50		80.80	110	90	80	110	80	84			
				Day 35	08/08/91	36.60		81.10	120	80	72	120	80	72			
				Day 42	15/08/91	36.80		80.10	120	80	80	120	75	84			
16	16	Imipramine	Male	Screen	02/12/91	37.00	16		120	80	64	130	75	70			
				Day 0	02/12/91	37.00		95.00	120	80	74	120	80	80			
				Day 7	16/12/91	36.60		95.00	120	85	78	120	80	80			
				Day 14	30/12/91	36.80		95.40	120	90	76	105	90	82			
				Day 21	30/12/91	37.80		95.00	115	80	90	110	80	100			
				Day 28	06/01/92	36.60		94.00	100	80	92	100	80	100			
				Day 35	10/01/92	36.80		94.00	115	80	105	85	86				
				Day 42	20/01/92	36.80		94.00	120	85	86	110	85	94			
20	17	Reboxetine	Male	Screen	20/05/92	36.50	16		115	80	68	110	70	72			
				Day 0	20/05/92	36.80		65.00	115	80	80	110	70	72			
				Day 7	27/05/92	36.80		65.40	110	75	75	105	75	96			
				Day 14	03/06/92	36.60		64.00	125	75	76	105	80	88			
				Day 21	11/06/92	36.60		65.00	110	80	72	100	80	84			
				Day 28	17/06/92	36.60		65.00	115	75	76	100	80	88			
				Day 35	24/06/92	36.60		64.00	105	80	76	130	85	84			
				Day 42	02/07/92	36.60		64.00	95	70	80	85	65	92			
								Screen	23/06/92	36.80		110	80	80	105	80	88
409	18	Reboxetine	Male	Day 0	23/06/92	36.80		82.00	110	80	80	105	80	88			
				Day 7	30/06/92	36.60		82.50	120	85	88	105	70	100			
				Day 14	06/07/92	36.60		82.00	130	85	90	135	80	105			
				Day 21	13/07/92	36.60		81.70	115	80	92	100	80	98			
				Day 28	20/07/92	36.60		81.30	120	75	84	105	80	96			
				Day 35	27/07/92	36.60		81.60	115	85	86	100	85	96			
				Day 42	03/08/92	36.60		81.50	115	80	80	105	75	86			
								Screen	05/12/91	37.00	16		135	95	78	140	100
								Day 0	05/12/91	37.00		68.00	130	95	80	140	100
				Day 7	16/12/91	36.80		68.00	130	90	74	135	85				
				Day 14	23/12/91	36.60		68.00	130	95	84	145	100				
				Day 28	06/01/92	36.80		67.00	135	90	86	120	90				
				Day 42	20/01/92	36.60		65.00	125	80	100	120	80				
410	10	Placebo	Male	Screen	10/02/92	36.80		115	75	80	120	80	92				
				Day 0	14/02/92	36.90		64.00	110	80	76	130	90	86			
				Day 7	20/02/92	37.00		62.00	120	80	78	120	85	78			
				Day 14	27/02/92	36.80		61.00	125	80	72	120	85	72			
				Day 21	05/03/92	36.80		61.00	115	80	72	130	95	76			

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60

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (kg)	BLOOD PRESSURE AND HEART RATE					
									Lying			Standing		
						S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)			
13	410	Placebo	Male	Day 28	12/03/92	36.80		61.00	125	90	80	120	90	76
				Day 35	19/03/92	36.80		61.00	120	80	72	110	90	84
				Day 42	26/03/92	36.80		61.00	115	90	76	105	85	84
2060	411	Imipramine	Female	Screen	26/03/92	36.80	20		100	60	80	90	60	88
				Day 0	26/03/92	36.80		46.70	100	60	80	90	60	88
				Day 7	06/04/92	36.80		48.00	105	60	84	60	86	86
				Day 14	13/04/92	36.60		47.20	110	60	68	100	55	74
				Day 21	22/04/92	36.80		49.20	100	60	60	60	60	82
				Day 28	27/04/92	36.50		47.50	100	70	78	95	65	82
				Day 35	04/05/92	36.60		47.50	100	70	82	90	80	82
				Day 42	11/05/92	36.40		47.80	110	60	92	85	60	104
				Screen	14/09/92	36.80	14		120	90	80	130	100	86
14	19	Reboxetine	Female	Day 0	14/09/92	36.40		87.20	123	90	80	130	100	86
				Day 7	21/09/92	36.80		87.20	120	95	84	130	110	94
				Day 14	29/09/92	36.60		85.50	115	90	80	110	105	88
				Day 21	05/10/92	36.40		87.20	110	80	68	100	70	76
				Day 42	28/10/92	36.60		88.00	140	95	80	155	100	84
				Screen	03/04/92	37.00	12		130	100	92	140	100	90
				Day 0	10/04/92	36.50		89.00	150	90	80	130	80	80
				Day 7	17/04/92	36.00		85.70	140	90	82	120	90	80
				Day 14	24/04/92	36.50		87.70	110	70	100	100	60	60
20	20	Imipramine	Female	Day 21	01/05/92	36.50		86.00	110	70	90	100	70	92
				Day 28	07/05/92	37.00		85.70	140	120	80	90	80	82
				Screen	27/04/92	37.00	16		140	90	86	120	70	80
				Day 0	29/04/92	36.00		85.00	145	80	80	120	70	70
				Day 7	06/05/92	36.00		86.50	120	80	100	105	70	100
				Day 14	13/05/92	36.50		85.60	140	70	100	100	70	102
				Day 21	20/05/92	36.50		87.70	150	80	70	135	80	70
				Day 28	27/05/92	36.00		88.00	120	80	60	150	90	80
				Day 35	02/06/92	36.60		91.50	160	90	88	130	80	90
21	21	Imipramine	Female	Day 42	10/06/92	37.00		91.00	150	90	88	130	80	86
				Screen	15/07/92	39.00	12		160	90	100	140	90	110
				Day 0	20/07/92	36.40		83.00	160	90	100	140	90	112
				Day 7	27/07/92	36.00		82.70	130	95	100	125	90	96
				Day 14	03/08/92	36.60		83.00	100	75	92	110	80	94
				Day 21	12/08/92	36.50		83.70	120	80	90	120	80	90
				Day 28	17/08/92	36.50		84.00	110	70	92	100	70	94
				Day 35	24/08/92	36.10		86.00	120	80	92	120	80	80

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE					
									S.B.P. (mmHg)	D.B.P. (mmHg)	lying Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	standing Heart Rate (beats/min)
15	25	Reboxetine	Female	Screen	17/06/91	36.60	15		138	80	90	136	80	86
				Day 0	18/06/91	36.60		65.00	138	80	90	136	80	86
				Day 7	25/06/91	36.60		65.00	140	80	92	142	80	96
				Day 14	02/07/91	36.60		65.50	136	78	94	146	80	96
				Day 21	09/07/91	36.40		65.00	140	80	90	136	80	90
				Day 28	16/07/91	36.60		64.50	142	84	86	140	80	90
				Day 35	23/07/91	36.80		65.00	140	82	88	136	84	86
				Day 42	30/07/91	36.80		65.00	140	86	90	136	84	94
				Screen	17/06/91	36.40	12		134	90	80	132	94	80
				Day 0	20/06/91	36.40		80.00	134	90	80	132	94	80
26	26	Placebo	Male	Day 7	27/06/91	36.40		80.00	134	92	78	132	90	84
				Day 14	04/07/91	36.40		79.00	134	90	84	132	92	80
				Day 21	11/07/91	36.60		79.00	134	82	84	128	80	86
				Day 28	18/07/91	36.60		78.00	134	86	90	130	86	92
				Day 35	25/07/91	36.80		77.50	140	88	92	136	88	90
				Day 42	01/08/91	36.60		76.00	134	90	86	128	90	88
				Screen	27/06/91	36.40	13		104	74	78	102	74	76
				Day 0	02/07/91	36.40		49.00	104	74	78	102	74	76
				Day 7	09/07/91	36.60		41.00	104	70	72	100	70	76
				Day 14	17/07/91	36.40		41.00	98	70	76	100	72	76
27	27	Imipramine	Female	Day 21	23/07/91	36.80		78.00	100	70	70	96	72	68
				Day 28	30/07/91	36.40		41.50	104	74	70	106	74	74
				Day 35	06/08/91	36.60		42.00	120	80	76	120	80	74
				Day 42	13/08/91	36.40		43.00	110	78	72	108	78	72
				Screen	27/06/91	36.40	13		104	74	78	102	74	76
				Day 0	02/07/91	36.40		49.00	104	74	78	102	74	76
				Day 7	09/07/91	36.60		41.00	104	70	72	100	70	76
				Day 14	17/07/91	36.40		41.00	98	70	76	100	72	76
				Day 21	23/07/91	36.80		78.00	100	70	70	96	72	68
				Day 28	30/07/91	36.40		41.50	104	74	70	106	74	74
28	28	Reboxetine	Female	Day 35	06/08/91	36.60		79.00	120	80	76	120	80	74
				Day 42	13/08/91	36.40		43.00	110	78	72	108	78	72
				Screen	06/08/91	36.60	12		108	70	68	110	74	70
				Day 0	08/08/91	36.60		82.00	108	70	68	110	74	70
				Day 7	15/08/91	36.60		81.00	110	70	80	110	74	74
				Day 14	22/08/91	36.40		80.00	124	80	82	120	80	82
				Day 21	29/08/91	36.40		79.50	116	78	104	110	80	106
				Day 28	05/09/91	36.40		79.00	114	70	82	118	74	84
				Day 35	12/09/91	36.40		79.00	118	76	86	114	80	100
				Day 42	20/09/91	36.80		79.80	120	70	86	120	74	86
29	29	Placebo	Male	Screen	29/08/91	36.40	14		122	82	90	120	80	88
				Day 0	29/08/91	36.40		87.00	122	82	90	120	80	88
				Day 7	05/09/91	36.80		88.50	130	84	132	94	84	
				Day 14	13/09/91	36.60		89.00	124	88	126	90	76	
				Day 21	19/09/91	36.40		90.00	128	86	126	90	82	

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62

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (°C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Lying Heart Rate (beats/min)	Standing Heart Rate (beats/min)			
15	30	Imipramine	Female	Screen	03/09/91	36.40	12	85.00	108	80	76	106	80	80	
				Day 0	03/09/91	36.40		85.00	108	80	76	106	80	80	80
				Day 7	10/09/91	36.60		84.00	110	80	82	110	82	80	86
				Day 14	17/09/91	36.40		84.00	114	80	84	110	80	88	88
				Day 21	24/09/91	36.80		84.00	118	80	86	116	84	90	90
				Day 28	01/10/91	36.40		84.00	110	80	88	106	80	90	90
	Day 35	08/10/91	36.60		84.50	114	84	80	116	84	84	84			
	Day 42	15/10/91	36.40		83.50	112	80	94	114	82	82	90			
	403	Imipramine	Female	Screen	04/10/91	36.40	14	61.00	160	90	76	138	86	78	
				Day 0	04/10/91	36.40		61.00	160	90	76	138	86	78	
				Day 7	11/10/91	36.60		61.50	130	90	86	130	88	80	
				Day 14	18/10/91	36.40		61.00	104	80	84	100	80	88	
				Day 21	25/10/91	36.60		60.80	114	80	86	104	80	88	
				Day 28	31/10/91	36.40		60.80	110	80	86	104	76	90	
	Day 35	08/11/91	36.60		60.00	116	80	82	114	80	78				
Day 42	14/11/91	36.40		60.00	116	80	96	100	80	100					
404	Reboxetine	Female	Screen	08/10/91	36.80	13	67.00	120	76	78	118	76	76		
			Day 0	08/10/91	36.80		67.00	120	76	78	118	76	76		
			Day 7	15/10/91	36.80		67.00	104	70	86	102	70	90		
			Day 14	22/10/91	36.60		67.50	100	70	90	104	72	88		
			Day 21	29/10/91	36.80		68.00	108	72	80	104	70	82		
			Day 28	05/11/91	36.80		68.00	100	76	80	104	78	80		
405	Placebo	Female	Screen	11/11/91	36.40	12	56.50	120	80	68	116	80	72		
			Day 0	11/11/91	36.40		56.50	120	80	68	116	80	72		
			Day 7	18/11/91	36.80		56.50	104	76	74	102	76	76		
			Day 14	25/11/91	36.80		56.50	100	70	70	102	70	72		
			Day 21	02/12/91	36.60		55.50	96	70	78	96	70	80		
			Day 28	10/12/91	36.60		56.50	100	70	70	96	70	80		
Day 35	16/12/91	36.60		56.50	94	70	76	94	72	76					
Day 42	23/12/91	36.80		56.50	100	74	72	102	74	70					
406	Imipramine	Male	Screen	27/11/91	36.80	16	77.00	114	82	86	114	84	86		
			Day 0	27/11/91	36.80		77.00	114	82	86	114	84	86		
			Day 7	03/12/91	36.80		78.00	126	90	98	120	90	100		
			Day 14	10/12/91	36.80		78.00	134	92	90	124	90	88		
			Day 21	17/12/91	36.80		78.00	136	90	96	132	92	94		
			Day 28	24/12/91	36.60		78.00	124	90	88	120	90	88		
Day 35	31/12/91	36.60		79.00	126	90	88	124	90	88					
Day 42	07/01/92	36.80		80.00	120	90	86	114	86	86					
407	Reboxetine	Female	Screen	02/12/91	36.60	14	126	82	70	130	80	72			
			Day 0	02/12/91	36.60		126	82	70	130	80	72			

2062

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63

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE						
									S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	standing			
15	407	Reboxetine	Female	Day 0	03/12/91	36.60		52.50	126	82	70	130	80	72	
				Day 7	10/12/91	36.60		52.00	106	76	78	104	76	82	82
				Day 14	17/12/91	36.80		52.50	104	74	86	102	74	74	88
				Day 21	24/12/91	36.80		52.50	104	74	86	104	70	80	90
				Day 28	31/12/91	36.80		53.00	110	74	80	110	110	76	80
	Day 35	07/01/92	36.80		52.00	112	80	78	114	114	78	82			
	Day 42	14/01/92	36.80		53.50	116	80	80	112	112	80	84			
	408	Placebo	Female	Screen	20/01/92	36.90	18		110	70	72	105	66	72	
				Day 0	20/01/92	36.90		80.00	110	70	72	105	66	72	
				Day 7	28/01/92	36.80		78.50	114	80	90	110	80	92	
				Day 14	03/02/92	36.80		76.50	110	78	96	106	80	96	
				Day 21	10/02/92	36.80		78.00	120	80	86	114	80	86	
	Day 28	17/02/92	36.80		79.00	120	80	98	106	74	96				
	Day 35	23/02/92	37.00		77.50	110	84	72	110	84	70				
	Day 42	04/03/92	36.80		76.00	118	80	78	114	114	80	80			
418	Placebo	Female	Screen	30/01/92	36.60	14		120	70	76	120	68	76		
			Day 0	30/01/92	36.60		58.50	120	70	76	120	68	76		
			Day 7	06/02/92	36.80		58.50	124	80	84	120	80	86		
			Day 14	13/02/92	36.60		58.00	122	76	80	124	78	80		
			Day 21	20/02/92	36.60		59.00	130	70	80	126	70	88		
Day 28	27/02/92	36.80		58.00	122	76	80	112	76	80					
Day 35	05/03/92	36.60		57.50	120	76	74	122	76	76					
Day 42	12/03/92	36.70		58.00	120	78	74	122	78	74					
419	Placebo	Female	Screen	27/04/92	36.80	16		100	70	76	102	70	80		
			Day 0	28/04/92	36.40		56.50	100	70	76	102	70	80		
			Day 7	05/05/92	36.60		56.50	104	70	74	100	72	76		
			Day 14	12/05/92	36.70		56.50	108	70	76	108	72	76		
			Day 21	19/05/92	36.90		56.00	106	72	76	102	74	74		
Day 28	26/05/92	36.90		57.50	110	70	76	106	74	78					
Day 35	02/06/92	36.80		58.00	108	72	82	106	74	78					
Day 42	09/06/92	36.80		58.50	110	74	74	106	74	74					

2063

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date Value	Abnormality	
1	1	Imipramine	Female	10/04/91	22/05/91	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	10/04/91 01/05/91 22/05/91	Normal Abnormal Abnormal	SINUS TACHYCARDIA (> 100) SINUS TACHYCARDIA (> 100)
2	2	Reboxetine	Male	15/04/91	27/05/91	Screen Day 21 Day 42	-4 21 42	Screening 1-21 days 22-42 days	11/04/91 06/05/91 27/05/91	Normal Normal Normal	
3	3	Imipramine	Male	06/05/91	16/06/91	Screen Day 21 Day 42	-4 21 42	Screening 1-21 days 22-42 days	02/05/91 27/05/91 17/06/91	Abnormal Abnormal Normal	SINUS BRADYCARDIA (< 60) SINUS BRADYCARDIA (< 60)
4	4	Placebo	Male	04/06/91	16/07/91	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	04/06/91 25/06/91 16/07/91	Normal Abnormal Abnormal	SINUS BRADYCARDIA (< 60) SINUS BRADYCARDIA (< 60)
5	5	Reboxetine	Female	12/06/91	02/07/91	Screen Day 21	0 20	Screening 1-21 days	12/06/91 02/07/91	Abnormal Normal	SINUS TACHYCARDIA (> 100)
6	6	Placebo	Female	23/05/91	05/07/91	Screen Day 21 Day 42	1 21 46	Screening 1-21 days 22-42 days	24/05/91 13/06/91 08/07/91	Normal Normal Normal	
7	7	Reboxetine	Female	27/08/91	08/10/91	Screen	1	Screening	28/08/91	Normal	
8	8	Placebo	Male	05/09/91	19/10/91	Screen Day 42	0 46	Screening 22-42 days	05/09/91 21/10/91	Abnormal Normal	SINUS TACHYCARDIA (> 100)
9	9	Reboxetine	Female	27/11/91	06/01/92	Screen Day 42	0 40	Screening 22-42 days	27/11/91 06/01/92	Abnormal Normal	SINUS BRADYCARDIA (< 60)
10	10	Placebo	Male	24/09/91	04/11/91	Screen Day 21 Day 42	1 21 41	Screening 1-21 days 22-42 days	25/09/91 15/10/91 04/11/91	Normal Normal Normal	
11	11	Imipramine	Female	10/10/91	13/10/91	Screen	0	Screening	10/10/91	Normal	
12	12	Imipramine	Female	18/10/91	30/11/91	Screen Day 42	3 46	Screening 22-42 days	21/10/91 03/12/91	Normal Abnormal	SINUS BRADYCARDIA (< 60)

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2

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.	
				Start date	End date				Date	Value
1	412	Reboxetine	Male	13/11/91	23/12/91	Screen Day 21	-1	Screening	12/11/91	Normal
						Screen Day 42	22	1-21 days	05/12/91	Normal
	413	Placebo	Male	09/12/91	20/01/92	Screen Day 21	-6	Screening	03/12/91	Normal
						Screen Day 42	21	1-21 days	30/12/91	Normal
20651	414	Imipramine	Female	22/01/92	29/01/92	Screen	-4	Screening	18/01/92	Normal
						Screen Day 21	0	Screening	14/01/92	Normal
	415	Imipramine	Male	14/01/92	27/02/92	Screen Day 21	23	1-21 days	06/02/92	Normal
						Screen Day 42	44	22-42 days	27/02/92	Normal
2/1	421	Imipramine	Male	27/02/92	09/04/92	Screen Day 21	0	Screening	27/02/92	Normal
						Screen Day 42	21	1-21 days	19/03/92	Normal
	422	Imipramine	Male	05/08/92	17/09/92	Screen Day 21	21	1-21 days	26/08/92	Normal
						Screen Day 42	44	22-42 days	18/09/92	Normal
2/2	49	Placebo	Female	18/05/91	28/06/91	Screen Day 21	-1	Screening	17/05/91	Normal
						Screen Day 42	23	1-21 days	10/06/91	Normal
	50	Reboxetine	Female	27/12/91	06/02/92	Screen Day 21	-3	Screening	24/12/91	Normal
						Screen Day 42	20	1-21 days	16/01/92	Abnormal
2/2	51	Imipramine	Female	02/02/92	15/03/92	Screen Day 21	-5	Screening	28/01/92	Normal
						Screen Day 42	23	1-21 days	23/02/92	Abnormal
	43	Imipramine	Female	18/04/91	16/05/91	Screen Day 28	-7	Screening	11/04/91	Normal
						Screen Day 28	28	22-42 days	16/05/91	Normal

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3

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0
ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date Value	Abnormality
				Start date	End date					
2/2	44	Imipramine	Female	19/07/91	29/08/91	Screen	-7	Screening	12/07/91	Normal
						Day 21	20	1-21 days	08/08/91	Normal
	Day 42	40	22-42 days	28/08/91	Normal					
	45	Reboxetine	Female	08/09/91	20/10/91	Screen	-12	Screening	27/08/91	Abnormal
Day 21						22	1-21 days	30/09/91	Normal	ATRIAL ECTOPIC BEATS - OCCASIONAL
Day 42						43	22-42 days	21/10/91	Abnormal	SINUS BRADYCARDIA (< 60)
46	Placebo	Female	26/09/91	23/10/91	Screen	-8	Screening	18/09/91	Normal	
					Day 28	27	22-42 days	23/10/91	Normal	
2/3	47	Placebo	Female	24/03/92	04/05/92	Screen	-11	Screening	13/03/92	Normal
						Day 21	21	1-21 days	14/04/92	Normal
	Day 42	44	22-42 days	07/05/92	Normal					
	48	Reboxetine	Female	07/04/92	19/05/92	Screen	-4	Screening	03/04/92	Normal
Day 21						21	1-21 days	28/04/92	Normal	
Day 42	43	22-42 days	20/05/92	Normal						
2/3	36/A	Imipramine	Male	07/03/91	17/04/91	Screen	1	Screening	08/03/91	Normal
						Day 21	21	1-21 days	28/03/91	Normal
	Day 42	41	22-42 days	17/04/91	Normal					
	37	Reboxetine	Female	27/03/91	07/05/91	Screen	-9	Screening	18/03/91	Normal
Day 21						20	1-21 days	16/04/91	Normal	
Day 42	47	22-42 days	13/05/91	Normal						
38	Placebo	Male	14/08/91	25/09/91	Screen	-2	Screening	12/08/91	Normal	
					Day 21	22	1-21 days	05/09/91	Normal	
Day 42	55	22-42 days	08/10/91	Normal						
39	Imipramine	Female	10/08/91	20/09/91	Screen	-4	Screening	06/08/91	Normal	
					Day 21	20	1-21 days	30/08/91	Normal	
Day 42	38	22-42 days	17/09/91	Normal						
40	Reboxetine	Female	24/10/91	04/12/91	Screen	0	Screening	24/10/91	Normal	
					Day 21	21	1-21 days	14/11/91	Normal	
Day 42	42	22-42 days	05/12/91	Normal						

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20324/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	Date Value	Abnormality	
				Start date	End date						
2/3	41	Placebo	Male	05/10/91	13/11/91	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	26/09/91 24/10/91 14/11/91	Normal Normal Normal	
	42	Imipramine	Female	19/05/92	30/06/92	Screen Day 21 Day 42	-12 21 49	Screening 1-21 days 22-42 days	07/05/92 09/06/92 07/07/92	Normal Normal Normal	
2/4	31	Placebo	Male	26/03/91	05/05/91	Screen Day 21 Day 42	-6 20 34	Screening 1-21 days 22-42 days	20/03/91 15/04/91 29/04/91	Normal Normal Normal	
	32	Reboxetine	Male	26/10/91	06/12/91	Screen Day 21 Day 42	-10 20 41	Screening 1-21 days 22-42 days	16/10/91 15/11/91 06/12/91	Abnormal Abnormal Abnormal	ATRIAL FIBRILLATION / FLUTTER ATRIAL FIBRILLATION / FLUTTER ATRIAL FIBRILLATION / FLUTTER
	33	Imipramine	Male	29/05/91	10/07/91	Screen Day 21 Day 42	-2 21 77	Screening 1-21 days 22-42 days	27/05/91 19/06/91 14/08/91	Normal Normal Normal	
	34	Placebo	Female	17/04/92	28/05/92	Screen Day 21 Day 42	-7 24 42	Screening 1-21 days 22-42 days	10/04/92 11/05/92 29/05/92	Normal Normal Normal	
	35	Reboxetine	Female	15/09/92	26/10/92	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	08/09/92 06/10/92 27/10/92	Normal Normal Normal	
	36	Imipramine	Female	12/02/92	24/03/92	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	05/02/92 04/03/92 25/03/92	Normal Normal Normal	
2/5	73	Placebo	Male	07/02/92	20/03/92	Screen Day 21 Day 42	-4 21 42	Screening 1-21 days 22-42 days	03/02/92 28/02/92 20/03/92	Normal Normal Normal	
	74	Reboxetine	Male	21/06/92	01/08/92	Screen Day 21 Day 42	-4 21 41	Screening 1-21 days 22-42 days	17/06/92 12/07/92 01/08/92	Normal Abnormal Normal	SINUS TACHYCARDIA (> 100)

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5

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.	
				Start date	End date				Date	Value
2/5	75	Imipramine	Male	11/09/92	22/10/92	Screen Day 21	-7	Screening	04/09/92	Normal
						Day 42	20	1-21 days	01/10/92	Normal
	76	Imipramine	Female	15/09/92	26/10/92	Screen Day 21	-3	Screening	12/09/92	Normal
						Day 42	22	1-21 days	07/10/92	Normal
	77	Placebo	Male	22/09/92	02/11/92	Screen Day 21	-6	Screening	16/09/92	Normal
						Day 42	20	1-21 days	12/10/92	Normal
	78	Reboxetine	Female	10/10/92	19/11/92	Screen Day 21	-9	Screening	01/10/92	Normal
						Day 42	19	1-21 days	29/10/92	Normal
2/6	55	Reboxetine	Female	12/06/92	23/07/92	Screen Day 42	4	Screening	16/06/92	Normal
							39	22-42 days	21/07/92	Normal
	56	Reboxetine	Female	12/06/92	23/07/92	Screen Day 42	4	Screening	16/06/92	Normal
							42	22-42 days	24/07/92	Abnormal
	57	Imipramine	Female	05/05/92	15/06/92	Screen Day 42	-5	Screening	30/04/92	Normal
							42	22-42 days	16/06/92	Normal
	58	Placebo	Female	18/05/92	29/06/92	Screen Day 42	0	Screening	18/05/92	Normal
							36	22-42 days	23/06/92	Normal
	59	Placebo	Male	27/05/92	23/06/92	Screen	7	Screening	03/06/92	Normal
							-39	Screening	03/06/92	Normal
	60	Imipramine	Female	12/05/92	22/06/92	Screen Day 42	42	22-42 days	23/06/92	Normal
							1	Screening	06/03/91	Normal
3/1	61	Imipramine	Male	05/03/91	08/04/91	Screen Day 21	20	1-21 days	25/03/91	Abnormal
							-4	Screening	12/04/91	Normal
	62	Imipramine	Female	16/04/91	26/05/91	Screen Day 21	21	1-21 days	07/05/91	Normal

2068

ATRIAL ECTOPIC BEATS - OCCASIONAL

EIGHT BUNDLE BRANCH BLOCK

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6

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECC TRACINGS

Centre	Patient	Treatment	Sex	-Treatment period-		Visit	days of treat.	Assessment	E.C.G.	
				Start date	End date				Date	Value
3/1	62	Imipramine	Female	16/04/91	26/05/91	Day 42	41	22-42 days	27/05/91	Normal
	63	Placebo	Male	13/05/91	23/06/91	Screen Day 21 Day 42	-3 21 42	Screening 1-21 days 22-42 days	10/05/91 03/06/91 24/06/91	Normal Normal Normal
	64	Placebo	Female	14/03/91	24/04/91	Screen Day 21	0 27	Screening 1-21 days	14/03/91 10/04/91	Normal Normal
	65	Reboxetine	Male	16/09/91	27/10/91	Screen Day 21 Day 42	-5 21 42	Screening 1-21 days 22-42 days	11/09/91 07/10/91 26/10/91	Normal Normal Normal
	66	Reboxetine	Male	10/06/91	21/07/91	Day 21 Day 42	21 39	1-21 days 22-42 days	01/07/91 19/07/91	Normal Normal
2069	139	Imipramine	Male	03/09/91	12/09/91	Screen	-6	Screening	28/08/91	Normal
	140	Placebo	Male	12/09/91	23/10/91	Screen Day 21 Day 42	-2 21 74	Screening 1-21 days 22-42 days	10/09/91 03/10/91 25/11/91	Normal Normal Normal
	141	Placebo	Female	03/10/91	14/11/91	Screen Day 21 Day 42	-7 27 42	Screening 1-21 days 22-42 days	26/09/91 30/10/91 14/11/91	Normal Normal Normal
	142	Imipramine	Female	18/11/91	08/12/91	Screen	-4	Screening	14/11/91	Normal
	143	Reboxetine	Female	15/04/92	20/05/92	Screen	1	Screening	16/04/92	Normal
	144	Reboxetine	Female	09/06/92	22/07/92	Screen	-5	Screening	04/06/92	Normal
	451	Reboxetine	Female	20/01/92	01/02/92	Screen	-5	Screening	15/01/92	Normal
	452	Placebo	Male	22/01/92	04/03/92	Screen Day 21 Day 42	-7 21 50	Screening 1-21 days 22-42 days	15/01/92 12/02/92 12/03/92	Normal Normal Normal

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7

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0

E.C.G.

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
3/1	453	Imipramine	Female	29/01/92	10/03/92	Screen Day 42	-1 42	Screening 22-42 days	28/01/92 11/03/92	Normal Normal	
	454	Reboxetine	Male	17/02/92	01/04/92	Screen Day 21	-5 21	Screening 1-21 days	12/02/92 09/03/92	Normal Normal	
	455	Placebo	Female	11/03/92	22/04/92	Screen Day 21	-7 31	Screening 1-21 days	04/03/92 11/04/92	Normal Normal	
	456	Imipramine	Female	25/03/92	03/04/92	Screen Day 14	-7 9	Screening 1-21 days	18/03/92 03/04/92	Normal Normal	
3/2	65/A	Reboxetine	Female	29/01/91	11/03/91	Screen Day 21 Day 42	-4 21 42	Screening 1-21 days 22-42 days	25/01/91 19/02/91 12/03/91	Abnormal Normal Abnormal	SINUS TACHYCARDIA (> 100) SINUS TACHYCARDIA (> 100)
3/3	67	Placebo	Male	18/07/91	28/08/91	Screen Day 21 Day 42	-2 20 41	Screening 1-21 days 22-42 days	16/07/91 07/08/91 28/08/91	Normal Normal Normal	
	68	Reboxetine	Male	21/01/92	02/03/92	Screen Day 21 Day 42	-7 20 41	Screening 1-21 days 22-42 days	14/01/92 10/02/92 02/03/92	Normal Normal Normal	
	69	Placebo	Male	04/02/92	16/03/92	Screen Day 21 Day 42	-4 20 41	Screening 1-21 days 22-42 days	31/01/92 24/02/92 16/03/92	Normal Normal Normal	
	70	Imipramine	Male	15/04/92	26/05/92	Screen Day 21 Day 42	-5 20 41	Screening 1-21 days 22-42 days	10/04/92 05/05/92 26/05/92	Normal Normal Normal	
	71	Imipramine	Female	16/04/92	27/05/92	Screen Day 21 Day 42	-2 20 41	Screening 1-21 days 22-42 days	14/04/92 06/05/92 27/05/92	Normal Normal Normal	
	72	Reboxetine	Male	25/07/92	04/09/92	Screen Day 21	-2 19	Screening 1-21 days	23/07/92 13/08/92	Normal Normal	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124-015
Listing No.: 21.0

ECC TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.	
				Start date	End date				Date	Value
3/3	72	Reboxetine	Male	25/07/92	04/09/92	Day 42	41	22-42 days	04/09/92	Normal
3/4	79	Imipramine	Female	04/05/91	15/06/91	Screen Day 21	-3	Screening	01/05/91	Normal
						Day 42	20	1-21 days	24/05/91	Normal
							44	22-42 days	17/06/91	Normal
	80	Imipramine	Male	01/09/91	24/09/91	Screen	-1	Screening	31/08/91	Normal
	81	Reboxetine	Female	17/05/91	27/06/91	Screen Day 21	-1	Screening	16/05/91	Normal
						Day 42	28	1-21 days	14/06/91	Normal
							42	22-42 days	28/06/91	Normal
	82	Placebo	Male	17/06/91	28/07/91	Screen Day 21	-3	Screening	14/06/91	Normal
						Day 42	21	1-21 days	08/07/91	Normal
							42	22-42 days	29/07/91	Normal
	83	Placebo	Male	17/06/91	24/06/91	Screen	-6	Screening	11/06/91	Abnormal
										RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
	84	Reboxetine	Female	09/10/91	23/11/91	Screen Day 21	-1	Screening	08/10/91	Normal
						Day 42	22	1-21 days	31/10/91	Normal
							34	22-42 days	12/11/91	Normal
	85	Imipramine	Female	29/10/91	08/12/91	Screen Day 21	-3	Screening	26/10/91	Normal
						Day 42	21	1-21 days	19/11/91	Abnormal
							41	22-42 days	09/12/91	Normal
	86	Imipramine	Male	03/12/91	15/01/92	Screen Day 42	0	Screening	03/12/91	Normal
							43	22-42 days	15/01/92	Normal
	87	Placebo	Female	09/12/91	19/01/92	Screen Day 21	-1	Screening	08/12/91	Normal
						Day 42	18	1-21 days	27/12/91	Normal
							42	22-42 days	20/01/92	Abnormal
	88	Placebo	Male	23/03/92	06/05/92	Screen Day 42	-5	Screening	18/03/92	Normal
							47	22-42 days	09/05/92	Normal
	89	Reboxetine	Female	26/03/92	06/05/92	Screen Day 21	-3	Screening	23/03/92	Normal
						Day 42	42	1-21 days	07/04/92	Normal
							47	22-42 days	12/05/92	Normal

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PHARMACIA CIS BRD
 REBOXTINE - PROPOSAL 20104-015
 Listing No.: 21.9
 ECC TRAINING

Centre	Patient	Treatment	Sex	Treatment period			Visit	days of treat.	Assessment	E.C.G.	
				Start date	End date	ECG				Date	Value
3/4	98	Reboxetine	Male	28/06/92	08/06/92	Screen	0	Screening	28/06/92	Normal	
				Day 21	22	1-21 days	20/05/92	Normal			
				Day 42	57	22-42 days	24/06/92	Normal			
457	Female	Placebo	22/05/92	11/06/92	Screen	-3	Screening	19/05/92	Normal		
			Day 21	25	1-21 days	16/06/92	Normal				
458	Female	Reboxetine	26/05/92	09/06/92	Screen	-8	Screening	16/05/92	Normal		
459	Female	Placebo	02/06/92	19/07/92	Screen	-4	Screening	29/05/92	Normal		
460	Male	Reboxetine	19/08/92	28/08/92	Screen	-5	Screening	14/08/92	Normal		
461	Female	Imipramine	17/09/92	24/09/92	Screen	-2	Screening	15/09/92	Normal		
462	Female	Imipramine	29/09/92	08/10/92	Screen	0	Screening	29/09/92	Normal		
4/1	91	Imipramine	Female	12/10/91	22/11/91	Screen	-5	Screening	07/10/91	Normal	
				Day 42	21	1-21 days	07/08/91	Normal			
92	Female	Reboxetine	07/08/91	17/09/91	Screen	0	Screening	07/08/91	Normal		
			Day 21	21	1-21 days	28/08/91	Normal				
			Day 42	42	22-42 days	18/09/91	Normal				
93	Male	Placebo	03/07/91	16/08/91	Screen	-4	Screening	29/06/91	Normal		
			Day 21	20	1-21 days	29/07/91	Normal				
			Day 42	42	22-42 days	14/08/91	Abnormal	STIRUS BRADYCARDIA (< 60)			
94	Female	Placebo	05/07/91	13/08/91	Screen	-6	Screening	29/06/91	Normal		
			Day 21	19	1-21 days	24/07/91	Normal				
			Day 42	59	22-42 days	27/08/91	Normal				
95	Female	Imipramine	03/06/91	16/07/91	Screen	4	Screening	07/06/91	Normal		
			Day 21	24	1-21 days	29/06/91	Normal				
			Day 42	58	22-42 days	11/07/91	Normal				
96	Female	Reboxetine	04/09/91	16/10/91	Screen	-5	Screening	30/08/91	Normal		

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
4/1	96	Reboxetine	Female	04/09/91	16/10/91	Day 21 Day 42	28 1-21 days 49 22-42 days	02/10/91 23/10/91	Abnormal Normal	SINUS TACHYCARDIA (> 100)	
	115	Reboxetine	Female	05/05/92	16/06/92	Screen Day 21 Day 42	8 Screening 21 1-21 days 42 22-42 days	14/05/92 27/05/92 17/06/92	Normal Normal Normal		
	116	Imipramine	Female	16/05/92	22/05/92	Screen	-9 Screening	07/05/92	Normal		
	117	Imipramine	Female	03/09/91	14/10/91	Screen Day 21 Day 42	0 Screening 21 1-21 days 42 22-42 days	03/09/91 26/09/91 15/10/91	Normal Normal Abnormal	SINUS TACHYCARDIA (> 100)	
	118	Reboxetine	Female	23/05/92	03/07/92	Screen Day 21 Day 42	-8 Screening 20 1-21 days 41 22-42 days	15/05/92 12/06/92 03/07/92	Normal Normal Normal		
	119	Placebo	Female			Screen	Screening	25/11/91	Normal		
	120	Placebo	Female	31/07/92	11/09/92	Screen Day 21 Day 42	-49 Screening 25 1-21 days 53 22-42 days	12/06/92 25/08/92 22/09/92	Normal Normal Normal		
	145	Imipramine	Female	30/09/92	10/11/92	Screen Day 21 Day 42	-6 Screening 35 1-21 days 44 22-42 days	24/09/92 04/11/92 13/11/92	Normal Normal Normal		
	146	Placebo	Female	16/09/92	27/10/92	Screen Day 21 Day 42	-47 Screening 20 1-21 days 41 22-42 days	31/07/92 06/10/92 27/10/92	Normal Normal Normal		
	147	Reboxetine	Female	01/09/92	12/10/92	Screen Day 21 Day 42	-66 Screening 20 1-21 days 41 22-42 days	17/07/92 21/09/92 12/10/92	Normal Normal Normal		
	148	Imipramine	Female	26/09/92	06/11/92	Screen Day 21 Day 42	-15 Screening 23 1-21 days 44 22-42 days	11/09/92 19/10/92 09/11/92	Normal Normal Normal		

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11

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of		E.C.G.		
				Start date	End date		treat.	Assessment	Date	Value	Abnormality
4/1	149	Reboxetine	Male	30/09/92	10/11/92	Screen Day 21 Day 42	-7 21 41	Screening 1-21 days 22-42 days	23/09/92 24/10/92 10/11/92	Normal Normal Normal	
	150	Placebo	Male	30/09/92	10/11/92	Screen Day 21 Day 42	-6 20 40	Screening 1-21 days 22-42 days	24/09/92 20/10/92 09/11/92	Normal Normal Normal	
4/2	93/A	Placebo	Male	22/02/91	04/04/91	Screen Day 21 Day 42	1 21 42	Screening 1-21 days 22-42 days	23/02/91 15/03/91 05/04/91	Normal Normal Normal	
	99/A	Placebo	Male	27/03/91	07/05/91	Screen Day 21 Day 42	-1 20 33	Screening 1-21 days 22-42 days	26/03/91 16/04/91 29/04/91	Normal Normal Normal	
	104	Reboxetine	Male	22/05/91	02/07/91	Screen Day 21 Day 42	-2 20 41	Screening 1-21 days 22-42 days	20/05/91 11/06/91 02/07/91	Normal Normal Normal	
4/3	97	Placebo	Male	17/04/91	28/05/91	Screen Day 42	-6 41	Screening 22-42 days	11/04/91 28/05/91	Normal Normal	
	98	Reboxetine	Female	20/06/91	21/07/91	Screen Day 21	-2 26	Screening 1-21 days	18/06/91 16/07/91	Normal Normal	
	99	Placebo	Female	08/08/91	15/08/91	Screen	-1	Screening	07/08/91	Abnormal	OTHER
	100	Imipramine	Female	27/11/91	17/12/91	Screen	-6	Screening	21/11/91	Abnormal	ATRIAL ECTOPIC BEATS - OCCASIONAL
	101	Imipramine	Male	17/03/92	27/04/92	Screen Day 21 Day 42	-1 20 41	Screening 1-21 days 22-42 days	16/03/92 06/04/92 27/04/92	Normal Normal Normal	
4/4	109	Reboxetine	Female	08/06/91	19/07/91	Screen Day 21 Day 42	-5 19 73	Screening 1-21 days 22-42 days	03/06/91 27/06/91 20/08/91	Normal Normal Normal	
	110	Imipramine	Male	15/06/91	26/07/91	Screen	-4	Screening	11/06/91	Normal	

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2074

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0

EKG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	E.C.G.		
				Start date	End date			Date	Value	Abnormality
4/4	110	Imipramine	Male	15/06/91	26/07/91	Day 21	19	1-21 days	04/07/91	Normal
						Day 42	41	22-42 days	26/07/91	Normal
	111	Imipramine	Male	04/07/91	14/08/91	Screen	-7	Screening	27/06/91	Normal
						Day 21	20	1-21 days	24/07/91	Normal
	112	Placebo	Male	10/07/91	20/08/91	Day 42	41	22-42 days	14/08/91	Normal
						Screen	0	Screening	10/07/91	Normal
	113	Reboxetine	Male	31/08/91	11/10/91	Day 21	21	1-21 days	31/07/91	Normal
						Day 42	41	22-42 days	20/08/91	Normal
	114	Placebo	Female	20/11/91	31/12/91	Screen	-5	Screening	26/08/91	Normal
						Day 21	23	1-21 days	23/09/91	Normal
	115	Imipramine	Female	19/02/92	25/03/92	Day 42	41	22-42 days	11/10/91	Normal
						Screen	-13	Screening	07/11/91	Normal
	116	Placebo	Female	14/03/92	08/04/92	Day 21	21	1-21 days	11/12/91	Abnormal
						Day 42	41	22-42 days	31/12/91	Abnormal
	117	Imipramine	Female	13/02/92	25/03/92	Screen	-8	Screening	05/02/92	Normal
						Day 21	21	1-21 days	05/03/92	Normal
	118	Placebo	Female	14/03/92	08/04/92	Day 42	41	22-42 days	25/03/92	Normal
						Screen	-1	Screening	13/03/92	Normal
	119	Reboxetine	Female	28/04/92	11/05/92	Day 21	23	1-21 days	06/04/92	Normal
						Day 42	29	22-42 days	22/04/92	Normal
	120	Placebo	Female	11/09/92	29/09/92	Screen	-6	Screening	27/05/92	Normal
						Day 21	19	1-21 days	09/09/92	Normal
	121	Reboxetine	Female	28/04/92	08/06/92	Screen	-7	Screening	21/04/92	Normal
						Day 21	20	1-21 days	18/05/92	Normal
	122	Placebo	Female	11/09/92	29/09/92	Day 42	42	22-42 days	09/06/92	Normal
						Screen	-2	Screening	09/09/92	Normal
	123	Reboxetine	Male	07/10/92	17/11/92	Day 21	20	1-21 days	30/09/92	Normal
						Day 42	41	22-42 days	27/10/92	Normal
	124	Placebo	Female	14/03/92	08/04/92	Screen	-1	Screening	13/03/92	Normal
						Day 21	23	1-21 days	06/04/92	Normal
	125	Imipramine	Female	19/02/92	25/03/92	Day 42	29	22-42 days	22/04/92	Normal
						Screen	-7	Screening	21/04/92	Normal
	126	Reboxetine	Female	28/04/92	08/06/92	Day 21	20	1-21 days	18/05/92	Normal
						Day 42	42	22-42 days	09/06/92	Normal
	127	Placebo	Female	11/09/92	29/09/92	Screen	-2	Screening	09/09/92	Normal
						Day 21	19	1-21 days	30/09/92	Normal
	128	Reboxetine	Male	07/10/92	17/11/92	Screen	-7	Screening	30/09/92	Normal
						Day 21	20	1-21 days	27/10/92	Normal
	129	Placebo	Female	14/03/92	08/04/92	Day 42	41	22-42 days	17/11/92	Normal
						Screen	-1	Screening	13/03/92	Normal
	130	Imipramine	Female	19/02/92	25/03/92	Day 21	21	1-21 days	11/12/91	Abnormal
						Day 42	41	22-42 days	31/12/91	Abnormal
	131	Placebo	Female	14/03/92	08/04/92	Screen	-8	Screening	05/02/92	Normal
						Day 21	21	1-21 days	05/03/92	Normal
	132	Reboxetine	Female	28/04/92	08/06/92	Day 42	41	22-42 days	25/03/92	Normal
						Screen	-1	Screening	13/03/92	Normal
	133	Placebo	Female	11/09/92	29/09/92	Day 21	23	1-21 days	06/04/92	Normal
						Day 42	29	22-42 days	22/04/92	Normal
	134	Reboxetine	Female	28/04/92	08/06/92	Screen	-7	Screening	21/04/92	Normal
						Day 21	20	1-21 days	18/05/92	Normal
	135	Placebo	Female	11/09/92	29/09/92	Day 42	42	22-42 days	09/06/92	Normal
						Screen	-2	Screening	09/09/92	Normal
	136	Reboxetine	Male	07/10/92	17/11/92	Day 21	20	1-21 days	30/09/92	Normal
						Day 42	41	22-42 days	27/10/92	Normal

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
5/1	127	Reboxetine	Male	06/06/91	17/07/91	Screen	-6	Screening	31/05/91	Normal	
						Day 21	21	1-21 days	27/06/91	Normal	
						Day 42	42	22-42 days	18/07/91	Normal	
	128	Reboxetine	Female	14/06/91	25/07/91	Screen	-1	Screening	13/06/91	Normal	
						Day 21	21	1-21 days	05/07/91	Normal	
						Day 42	42	22-42 days	26/07/91	Normal	
	129	Placebo	Male	24/12/91	03/02/92	Screen	-4	Screening	20/12/91	Normal	
						Day 21	20	1-21 days	13/01/92	Normal	
						Day 42	41	22-42 days	03/02/92	Normal	
20076	130	Placebo	Male	05/03/92	15/04/92	Screen	-3	Screening	02/03/92	Normal	
						Day 21	20	1-21 days	25/03/92	Normal	
						Day 42	41	22-42 days	15/04/92	Normal	
	131	Imipramine	Female	21/03/92	30/04/92	Screen	-1	Screening	20/03/92	Normal	SINUS TACHYCARDIA (> 100)
						Day 21	20	1-21 days	10/04/92	Normal	
						Day 42	40	22-42 days	30/04/92	Abnormal	
5/2	132	Imipramine	Male	25/06/92	06/08/92	Screen	-1	Screening	24/06/92	Normal	SINUS TACHYCARDIA (> 100) ATRIAL ECTOPIC BEATS - OCCASIONAL VENTRICULAR ECTOPIC BEATS - OCCASIONAL SINUS TACHYCARDIA (> 100) ATRIAL ECTOPIC BEATS - OCCASIONAL VENTRICULAR ECTOPIC BEATS - OCCASIONAL
						Day 21	21	1-21 days	16/07/92	Normal	
						Day 42	46	22-42 days	10/08/92	Normal	
5/3	133	Placebo	Male	29/11/91	12/12/91	Screen	0	Screening	20/12/91	Abnormal	SINUS TACHYCARDIA (> 100) ATRIAL ECTOPIC BEATS - OCCASIONAL VENTRICULAR ECTOPIC BEATS - OCCASIONAL SINUS TACHYCARDIA (> 100) ATRIAL ECTOPIC BEATS - OCCASIONAL VENTRICULAR ECTOPIC BEATS - OCCASIONAL
						Day 21	21	1-21 days	10/01/92	Abnormal	
						Day 42	39	22-42 days	28/01/92	Normal	
5/3	134	Reboxetine	Female	06/12/91	16/01/92	Screen	-4	Screening	24/01/91	Normal	
						Day 21	14	1-21 days	11/02/91	Normal	
						Day 42	42	22-42 days	11/03/91	Normal	
	134	Reboxetine	Female	06/12/91	16/01/92	Screen	-4	Screening	25/11/91	Normal	
						Day 21	-3	Screening	03/12/91	Normal	
						Day 42	-3	Screening			

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0

ECC TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
5/3	134	Reboxetine	Female	06/12/91	16/01/92	Day 21 Day 42	21 41	1-21 days 22-42 days	27/12/91 16/01/92	Abnormal Normal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
	135	Imipramine	Female	10/01/92	20/02/92	Screen Day 42	-4 41	Screening 22-42 days	06/01/92 20/02/92	Abnormal Normal	SINUS BRADYCARDIA (< 60)
	136	Imipramine	Female	02/03/92	12/04/92	Screen Day 42	0 42	Screening 22-42 days	02/03/92 13/04/92	Normal Normal	
	137	Reboxetine	Female	15/05/92	25/06/92	Screen Day 21 Day 42	-4 21 41	Screening 1-21 days 22-42 days	11/05/92 05/06/92 25/06/92	Abnormal Normal Normal	SINUS BRADYCARDIA (< 60)
	138	Placebo	Female	15/05/92	16/05/92	Screen	-1	Screening	14/05/92	Normal	
6/1	151	Imipramine	Male	21/01/92	28/01/92	Screen Day 7	-5 13	Screening 1-21 days	16/01/92 03/02/92	Normal Normal	
	152	Reboxetine	Female	24/02/92	07/04/92	Screen Day 21 Day 42	-6 24 46	Screening 1-21 days 22-42 days	18/02/92 19/03/92 10/04/92	Normal Normal Normal	
	153	Reboxetine	Male	18/03/91	29/04/91	Screen Day 21 Day 42	-4 21 45	Screening 1-21 days 22-42 days	14/03/91 08/04/91 02/05/91	Normal Normal Normal	
	154	Imipramine	Female	30/03/92	06/04/92	Screen	-2	Screening	28/03/92	Normal	
	155	Placebo	Male	08/07/92	04/08/92	Screen Day 21 Day 28	-2 20 27	Screening 1-21 days 22-42 days	06/07/92 28/07/92 04/08/92	Normal Normal Normal	
	156	Placebo	Female	08/09/92	19/10/92	Screen Day 42	0 44	Screening 22-42 days	08/09/92 22/10/92	Normal Normal	
6/2	157	Reboxetine	Male	30/04/91	10/06/91	Screen Day 21 Day 42	-8 21 41	Screening 1-21 days 22-42 days	22/04/91 21/05/91 10/06/91	Normal Normal Normal	

2077

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
6/2	158	Imipramine	Female	24/11/91	05/01/92	Screen	-3	Screening	21/11/91	Normal	
						Day 21	20	1-21 days	14/12/91	Normal	
						Day 42	60	22-42 days	23/01/92	Normal	
	159	Imipramine	Male	14/07/91	24/08/91	Screen	-3	Screening	11/07/91	Normal	
						Day 21	24	1-21 days	07/08/91	Normal	
						Day 42	46	22-42 days	29/08/91	Normal	
	160	Placebo	Male	24/11/91	04/01/92	Screen	-2	Screening	22/11/91	Abnormal	RIGHT BUNDLE BRANCH BLOCK
						Day 21	20	1-21 days	14/12/91	Abnormal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
						Day 42	41	22-42 days	04/01/92	Abnormal	RIGHT BUNDLE BRANCH BLOCK
	161	Reboxetine	Female	20/02/92	18/03/92	Screen	-2	Screening	18/02/92	Normal	
						Day 21	20	1-21 days	11/03/92	Normal	
	162	Placebo	Male	10/07/91	13/07/91	Screen	-2	Screening	08/07/91	Normal	
						Screen	-17	Screening	09/12/91	Normal	
	169	Imipramine	Female	26/12/91	15/01/92	Screen	20	1-21 days	15/01/92	Normal	
						Day 21	20	1-21 days	15/01/92	Normal	
	170	Placebo	Male	01/11/91	15/11/91	Screen	-6	Screening	26/10/91	Normal	
						Screen	-105	Screening	08/04/92	Normal	
	171	Imipramine	Female	22/07/92	01/09/92	Screen	20	1-21 days	11/08/92	Normal	
						Day 21	56	22-42 days	16/09/92	Normal	
						Day 42	56	22-42 days	16/09/92	Normal	
	172	Reboxetine	Female	07/07/92	17/08/92	Screen	0	Screening	07/07/92	Normal	
						Day 21	20	1-21 days	27/07/92	Normal	
						Day 42	57	22-42 days	02/09/92	Normal	
	173	Placebo	Male	05/07/92	15/08/92	Screen	-4	Screening	01/07/92	Normal	
						Day 21	20	1-21 days	25/07/92	Normal	
	174	Reboxetine	Male	11/05/92	21/06/92	Screen	-6	Screening	05/05/92	Normal	
						Day 21	21	1-21 days	01/06/92	Normal	
						Day 42	47	22-42 days	27/06/92	Normal	

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

16

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
6/3	163	Reboxetine	Male	06/06/91	08/06/91	Screen	-6	Screening	31/05/91	Normal	
	164	Imipramine	Male	11/10/91	21/11/91	Screen Day 21 Day 42	-4 20 42	Screening 1-21 days 22-42 days	07/10/91 31/10/91 22/11/91	Normal Normal Normal	
	165	Imipramine	Female	16/10/91	26/11/91	Screen Day 21 Day 42	-6 20 41	Screening 1-21 days 22-42 days	10/10/91 05/11/91 26/11/91	Normal Normal Abnormal	SINUS TACHYCARDIA (> 100)
	166	Reboxetine	Female	25/10/91	29/10/91	Screen	-8	Screening	17/10/91	Normal	
	167	Placebo	Female	18/11/91	27/12/91	Screen Day 21 Day 42	-4 21 39	Screening 1-21 days 22-42 days	14/11/91 09/12/91 27/12/91	Normal Normal Normal	
	168	Placebo	Female	03/12/91	06/01/92	Screen Day 21	-16 19	Screening 1-21 days	17/11/91 22/12/91	Normal Normal	
	505	Imipramine	Female	03/12/91	17/12/91	Screen Day 14	-4	Screening	29/11/91 18/12/91	Normal Normal	
	506	Placebo	Female	08/01/92	19/02/92	Screen Day 21 Day 42	-2 21 42	Screening 1-21 days 22-42 days	06/01/92 29/01/92 19/02/92	Normal Normal Normal	
	507	Imipramine	Female	14/01/92	24/02/92	Screen Day 21 Day 42	-7 21 41	Screening 1-21 days 22-42 days	07/01/92 04/02/92 24/02/92	Normal Normal Normal	
	508	Reboxetine	Female	05/02/92	17/03/92	Screen Day 21 Day 42	-7 20 41	Screening 1-21 days 22-42 days	29/01/92 25/02/92 17/03/92	Normal Normal Normal	
	509	Placebo	Male	24/02/92	06/04/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	24/02/92 16/03/92 06/04/92	Normal Normal Normal	
	510	Reboxetine	Female	27/02/92	10/03/92	Screen	-13	Screening	14/02/92	Normal	

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2079

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
6/3	511	Imipramine	Female	19/03/92	21/04/92	Screen Day 21	0 19	Screening 1-21 days	19/03/92 07/04/92	Normal Abnormal	SINUS TACHYCARDIA (> 100)
	512	Placebo	Female	01/04/92	01/04/92	Screen	-5	Screening	27/03/92	Normal	
	513	Imipramine	Female	13/05/92	23/06/92	Screen Day 21 Day 42	-8 20 44	Screening 1-21 days 22-42 days	05/05/92 02/06/92 23/06/92	Normal Abnormal Abnormal	SINUS TACHYCARDIA (> 100) SINUS TACHYCARDIA (> 100)
7/02	181	Reboxetine	Male	27/01/92	08/03/92	Screen Day 21 Day 42	-10 21 42	Screening 1-21 days 22-42 days	17/01/92 17/02/92 09/03/92	Normal Normal Normal	
2000	182	Placebo	Male	23/11/91	03/01/92	Screen Day 21 Day 42	-1 20 41	Screening 1-21 days 22-42 days	22/11/91 13/12/91 03/01/92	Normal Abnormal Normal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL MYOCARDIAL ISCHEMIA
	183	Imipramine	Male	02/01/92	18/01/92	Screen Day 21	-3 20	Screening 1-21 days	30/12/91 22/01/92	Abnormal Normal	SINUS BRADYCARDIA (< 60)
	184	Imipramine	Female	27/01/92	08/03/92	Screen Day 21 Day 42	-4 21 42	Screening 1-21 days 22-42 days	23/01/92 17/02/92 09/03/92	Normal Normal Normal	
	185	Reboxetine	Male	10/04/92	05/05/92	Screen Day 21	-1 20	Screening 1-21 days	09/04/92 30/04/92	Normal Normal	
	186	Placebo	Male	16/04/92	27/05/92	Screen Day 21 Day 42	-1 20 44	Screening 1-21 days 22-42 days	15/04/92 06/05/92 27/05/92	Normal Abnormal Normal	SINUS BRADYCARDIA (< 60)
	535	Placebo	Male	15/04/92	26/05/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	15/04/92 06/05/92 27/05/92	Abnormal Abnormal Abnormal	SINUS BRADYCARDIA (< 60) SINUS BRADYCARDIA (< 60) SINUS BRADYCARDIA (< 60)
	536	Reboxetine	Female	08/05/92	18/06/92	Screen Day 21	0 21	Screening 1-21 days	08/05/92 29/05/92	Normal Normal	

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

18

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECC TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
7/02	536	Reboxetine	Female	08/05/92	18/06/92	Day 42	42	22-42 days	19/06/92	Normal	
7/03	187	Imipramine	Female	18/02/92	30/03/92	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	11/02/92 10/03/92 31/03/92	Normal Normal Normal	
	188	Placebo	Male	25/02/92	06/04/92	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	18/02/92 17/03/92 07/04/92	Normal Normal Normal	
	189	Placebo	Male	25/02/92	06/04/92	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	18/02/92 17/03/92 07/04/92	Normal Normal Normal	
	190	Reboxetine	Male	28/02/92	09/04/92	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	21/02/92 20/03/92 10/04/92	Normal Normal Normal	
	191	Imipramine	Female	03/03/92	10/04/92	Screen Day 21	-7 21	Screening 1-21 days	25/02/92 24/03/92	Abnormal Abnormal	SINUS TACHYCARDIA (> 100) SINUS TACHYCARDIA (> 100)
	192	Reboxetine	Female	10/03/92	20/04/92	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	03/03/92 31/03/92 21/04/92	Normal Normal Normal	
	523	Reboxetine	Female	06/05/92	16/06/92	Screen Day 21 Day 42	-8 20 41	Screening 1-21 days 22-42 days	28/04/92 26/05/92 16/06/92	Normal Normal Normal	
	524	Placebo	Female	06/05/92	16/06/92	Screen Day 21 Day 42	-8 20 41	Screening 1-21 days 22-42 days	28/04/92 26/05/92 16/06/92	Normal Normal Normal	
	525	Placebo	Female	06/05/92	16/06/92	Screen Day 21 Day 42	-8 20 41	Screening 1-21 days 22-42 days	28/04/92 26/05/92 16/06/92	Normal Normal Normal	
	526	Reboxetine	Female	06/05/92	16/06/92	Screen Day 21 Day 42	-28 20 41	Screening 1-21 days 22-42 days	08/04/92 26/05/92 16/06/92	Normal Normal Normal	

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090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0
ECG TRACINGS

		-Treatment period-			E.C.G.						
Centre	Patient	Treatment	Sex	Start date	End date	Visit	days of treat.	Assessment	Date	Value	Abnormality
7/03	527	Imipramine	Female	19/05/92	29/06/92	Screen Day 21 Day 42	-7 21 42	Screening 1-21 days 22-42 days	12/05/92 09/06/92 30/06/92	Normal Normal Normal	
	528	Imipramine	Female	19/05/92	22/06/92	Screen Day 21	-7 21	Screening 1-21 days	12/05/92 09/06/92	Normal Normal	
7/04	193	Placebo	Female	25/01/92	06/03/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	25/01/92 15/02/92 07/03/92	Normal Normal Normal	
	194	Reboxetine	Male	25/01/92	06/03/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	25/01/92 15/02/92 07/03/92	Normal Normal Normal	
2008	195	Placebo	Female	25/01/92	06/03/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	25/01/92 15/02/92 07/03/92	Normal Normal Normal	
2008	196	Reboxetine	Female	01/02/92	13/03/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	01/02/92 22/02/92 14/03/92	Normal Normal Normal	
	197	Imipramine	Male	01/02/92	13/03/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	01/02/92 22/02/92 14/03/92	Normal Normal Normal	
	198	Imipramine	Female	01/02/92	13/03/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	01/02/92 22/02/92 14/03/92	Normal Normal Normal	
	199	Imipramine	Male	28/03/92	08/05/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	28/03/92 18/04/92 09/05/92	Abnormal Abnormal Abnormal	RIGHT BUNDLE BRANCH BLOCK RIGHT BUNDLE BRANCH BLOCK RIGHT BUNDLE BRANCH BLOCK
	200	Placebo	Male	28/03/92	08/05/92	Screen Day 21 Day 42	0 21 42	Screening 1-21 days 22-42 days	28/03/92 18/04/92 09/05/92	Normal Normal Normal	

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

20

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0
ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
7/04	201	Reboxetine	Female	28/03/92	08/05/92	Screen	0	Screening	28/03/92	Normal	
						Day 21	21	1-21 days	18/04/92	Normal	
						Day 42	42	22-42 days	09/05/92	Normal	
	202	Reboxetine	Male	04/04/92	15/05/92	Screen	-3	Screening	01/04/92	Normal	
						Day 21	21	1-21 days	25/04/92	Normal	
						Day 42	42	22-42 days	16/05/92	Normal	
	203	Placebo	Female	04/04/92	15/05/92	Screen	-3	Screening	01/04/92	Normal	
						Day 21	21	1-21 days	25/04/92	Normal	
						Day 42	42	22-42 days	16/05/92	Normal	
	204	Imipramine	Female	04/04/92	15/05/92	Screen	-3	Screening	01/04/92	Normal	
						Day 21	21	1-21 days	25/04/92	Normal	
						Day 42	42	22-42 days	16/05/92	Normal	
7/05	205	Placebo	Male	27/01/92	08/03/92	Screen	-28	Screening	30/12/91	Normal	
						Day 21	21	1-21 days	17/02/92	Normal	
						Day 42	42	22-42 days	09/03/92	Normal	
	206	Imipramine	Female	28/01/92	09/03/92	Screen	-14	Screening	14/01/92	Normal	
						Day 21	21	1-21 days	18/02/92	Normal	
						Day 42	42	22-42 days	10/03/92	Normal	
	207	Imipramine	Female	28/01/92	09/03/92	Screen	-7	Screening	21/01/92	Normal	
						Day 21	21	1-21 days	10/03/92	Normal	
						Day 42	42	22-42 days			
	208	Reboxetine	Male	30/01/92	11/03/92	Screen	-6	Screening	24/01/92	Normal	
						Day 21	21	1-21 days	20/02/92	Normal	
						Day 42	42	22-42 days	12/03/92	Normal	
	209	Placebo	Male	05/02/92	17/03/92	Screen	-7	Screening	29/01/92	Normal	
						Day 21	21	1-21 days	28/02/92	Normal	
						Day 42	42	22-42 days	18/03/92	Normal	
	210	Reboxetine	Male	07/02/92	19/03/92	Screen	-4	Screening	03/02/92	Normal	
						Day 21	21	1-21 days	28/02/92	Normal	
						Day 42	42	22-42 days	20/03/92	Normal	

9550082

2003

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

21

PHARMACIA CNS RAD
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECC TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat. Assessment	E.C.G.		
				Start date	End date			Date	Value	Abnormality
7/05	541	Reboxetine	Female	17/03/92	27/04/92	Screen	-15	02/03/92	Normal	
						Day 21		07/04/92	Normal	
						Day 42		28/04/92	Normal	
542	542	Imipramine	Male	17/03/92	27/04/92	Screen	-15	02/03/92	Normal	
						Day 21		07/04/92	Normal	
						Day 42		28/04/92	Normal	
543	543	Imipramine	Male	18/03/92	28/04/92	Screen	-15	03/03/92	Normal	
						Day 21		08/04/92	Normal	
						Day 42		29/04/92	Normal	
544	544	Placebo	Female	24/03/92	04/05/92	Screen	-20	04/03/92	Normal	
						Day 21		14/04/92	Normal	
						Day 42		05/05/92	Normal	
545	545	Placebo	Male	25/03/92	05/05/92	Screen	-16	09/03/92	Normal	
						Day 21		15/04/92	Normal	
						Day 42		06/05/92	Normal	
546	546	Reboxetine	Female	25/03/92	05/05/92	Screen	-15	10/03/92	Normal	
						Day 21		15/04/92	Normal	
						Day 42		06/05/92	Normal	
7/07	529	Placebo	Female	18/02/92	30/03/92	Screen	-1	17/02/92	Normal	
						Day 21		10/03/92	Normal	
						Day 42		31/03/92	Normal	
530	530	Imipramine	Female	20/02/92	09/03/92	Screen	-3	17/02/92	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 14		12/03/92	Abnormal	
						Day 21		18/03/92	Normal	
531	531	Reboxetine	Female	24/02/92	05/04/92	Screen	-6	18/02/92	Normal	
						Day 21		16/03/92	Normal	
						Day 42		06/04/92	Normal	
532	532	Imipramine	Female	27/04/92	07/06/92	Screen	-4	23/04/92	Normal	
						Day 21		18/05/92	Normal	
						Day 42		09/06/92	Normal	

9550082

2084

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

22

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0
ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.	
				Start date	End date				Date	Value
7/07	533	Reboxetine	Male	04/05/92	14/06/92	Screen	-7	Screening	27/04/92	Normal
						Day 21	21	1-21 days	25/05/92	Normal
8	534	Placebo	Female	15/05/92	25/06/92	Day 42	42	22-42 days	15/06/92	Normal
						Screen	-3	Screening	12/05/92	Normal
8	211	Reboxetine	Female	13/05/91	26/05/91	Day 21	21	1-21 days	05/06/92	Normal
						Day 42	42	22-42 days	26/06/92	Normal
8	212	Placebo	Female	14/09/91	25/10/91	Screen	0	Screening	13/05/91	Normal
						Screening				
8	213	Imipramine	Male	22/11/91	24/11/91	Screening				
						Screening				
8	214	Reboxetine	Female	23/11/91	03/01/92	Screen	-13	Screening	10/11/91	Normal
						Screening				
8	215	Placebo	Female	18/02/92	30/03/92	Screening				
						Screening				
8	216	Imipramine	Male	27/03/92	07/05/92	Day 21	21	1-21 days	17/04/92	Normal
						Screening				
8	217	Reboxetine	Female	30/03/92	10/05/92	Screening				
						Screening				
8	218	Reboxetine	Female	09/04/92	20/05/92	Screen	-8	Screening	01/04/92	Normal
						Screening				
8	219	Placebo	Female	11/04/92	01/05/92	Screen	-8	Screening	03/04/92	Normal
						Screening				
8	220	Imipramine	Female	27/04/92	07/06/92	Screening				
						Screening				
8	221	Imipramine	Male	28/04/92	08/06/92	Screening				
						Screening				
8	222	Placebo	Female	28/04/92	08/06/92	Screening				
						Screening				
8	223	Imipramine	Female	11/05/92	21/06/92	Screening				
						Screening				

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23

PHARMACIA CMS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0
ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	E.C.G.	
				Start date	End date				Date	Value
8	224	Placebo	Female	07/09/92	18/10/92	Screen Day 42	-11 28	Screening 22-42 days	27/08/92 05/10/92	Normal Normal
	225	Placebo	Male	11/09/92	22/10/92	Screen Day 21	-6 21	Screening 1-21 days	05/09/92 02/10/92	Normal Normal
	226	Reboxetine	Male	23/09/92	03/11/92	Screen	-2	Screening	21/09/92	Normal
	227	Reboxetine	Male	25/09/92	05/11/92			Screening		
	228	Imipramine	Male	26/09/92	02/10/92			Screening		
	229	Imipramine	Female	30/09/92	10/11/92			Screening		
	230	Reboxetine	Female	28/09/92	08/11/92			Screening		
	231	Imipramine	Male	30/09/92	10/11/92	Screen Day 21 Day 42	-5 21 42	Screening 1-21 days 22-42 days	25/09/92 21/10/92 11/11/92	Normal Normal Normal
	232	Reboxetine	Male	02/10/92	12/11/92	Screen Day 42	-3 38	Screening 22-42 days	29/09/92 09/11/92	Normal Normal
	233	Placebo	Female	07/10/92	17/11/92	Screen Day 42	-9 33	Screening 22-42 days	28/09/92 09/11/92	Normal Normal
	234	Placebo	Female	07/10/92	17/11/92	Screen Day 42	-7 34	Screening 22-42 days	30/09/92 10/11/92	Normal Normal
8/A	235	Placebo	Female	14/10/92	24/11/92	Screen Day 21 Day 42	-26 21 41	Screening 1-21 days 22-42 days	18/09/92 04/11/92 24/11/92	Normal Normal Normal
	236	Placebo	Female	14/10/92	24/11/92	Screen Day 21 Day 42	-26 21 41	Screening 1-21 days 22-42 days	18/09/92 04/11/92 24/11/92	Normal Normal Normal

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24

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: Z1.0
ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
8/A	237	Reboxetine	Female	14/10/92	24/11/92	Screen	-26	Screening	18/09/92	Abnormal	RIPOLARIZATION DISTURBANCES
						Day 21	20	1-21 days	03/11/92	Abnormal	RIPOLARIZATION DISTURBANCES
						Day 42	41	22-42 days	24/11/92	Abnormal	RIPOLARIZATION DISTURBANCES
	238	Reboxetine	Female	14/10/92	24/11/92	Screen	-26	Screening	18/09/92	Normal	
						Day 21	21	1-21 days	04/11/92	Normal	
						Day 42	41	22-42 days	24/11/92	Normal	
	239	Imipramine	Female	16/10/92	26/11/92	Screen	-24	Screening	22/09/92	Abnormal	MYOCARDIAL ISCHEMIA
						Day 21	20	1-21 days	05/11/92	Abnormal	MYOCARDIAL ISCHEMIA
						Day 42	43	22-42 days	28/11/92	Abnormal	MYOCARDIAL ISCHEMIA
	240	Imipramine	Female	16/10/92	26/11/92	Screen	-24	Screening	22/09/92	Abnormal	LEFT AXIAL DEVIATION
						Day 21	20	1-21 days	05/11/92	Abnormal	LEFT AXIAL DEVIATION
						Day 42	41	22-42 days	26/11/92	Abnormal	LEFT AXIAL DEVIATION
2007	553	Placebo	Female	16/10/92	26/11/92	Screen	-23	Screening	23/09/92	Normal	
						Day 21	20	1-21 days	05/11/92	Normal	
						Day 42	41	22-42 days	26/11/92	Normal	
554	Reboxetine	Male	16/10/92	26/11/92	Screen	-24	Screening	22/09/92	Normal		
					Day 21	20	1-21 days	05/11/92	Normal		
					Day 42	41	22-42 days	26/11/92	Normal		
555	Reboxetine	Female	16/10/92	26/11/92	Screen	-24	Screening	22/09/92	Normal		
					Day 21	20	1-21 days	05/11/92	Normal		
					Day 42	41	22-42 days	26/11/92	Normal		
556	Imipramine	Male	16/10/92	26/11/92	Screen	-24	Screening	22/09/92	Normal		
					Day 21	20	1-21 days	05/11/92	Normal		
					Day 42	41	22-42 days	26/11/92	Normal		
9	241	Placebo	Female	07/02/91	17/02/91	Screen	-14	Screening	24/01/91	Normal	
						Screen	-11	Screening	07/02/91	Abnormal	CONDUCTION DISORDER
242	Reboxetine	Female	18/02/91	11/03/91	Screen	-22	1-21 days	12/03/91	Abnormal	CONDUCTION DISORDER	
					Screen	-5	Screening	15/02/91	Abnormal	RIPOLARIZATION DISTURBANCES	
243	Reboxetine	Female	20/02/91	06/03/91	Screen	-5	Screening	15/02/91	Abnormal	RIPOLARIZATION DISTURBANCES	
					Screen	-5	Screening	15/02/91	Abnormal	RIPOLARIZATION DISTURBANCES	

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
9	243	Reboxetine	Female	20/02/91	06/03/91	Day 14	14	1-21 days	06/03/91	Normal	
	244	Imipramine	Female	19/02/91	13/03/91	Screen Day 21	-5	Screening	14/02/91	Normal	
						Day 28	20	1-21 days	11/03/91	Abnormal	ATRIAL ECTOPIC BEATS - OCCASIONAL
							27	22-42 days	18/03/91	Normal	
	245	Imipramine	Female	22/02/91	04/04/91	Screen Day 21	-4	Screening	18/02/91	Abnormal	OTHER
							21	1-21 days	15/03/91	Abnormal	LEFT VENTRICULAR HYPERTROPHY
	246	Placebo	Female	22/02/91	17/03/91	Screen Day 21	-9	Screening	13/02/91	Abnormal	RIPOLARIZATION DISTURBANCES
						Day 28	21	1-21 days	15/03/91	Abnormal	SINUS BRADYCARDIA (< 60)
							25	22-42 days	19/03/91	Normal	
	247	Placebo	Female	25/02/91	26/03/91	Screen Day 21	-5	Screening	20/02/91	Abnormal	RIPOLARIZATION DISTURBANCES
							21	1-21 days	18/03/91	Abnormal	RIPOLARIZATION DISTURBANCES
	248	Placebo	Male	07/03/91	21/03/91	Screen Day 14	-3	Screening	04/03/91	Normal	
							15	1-21 days	22/03/91	Normal	
	249	Reboxetine	Female	08/03/91	11/03/91	Screen	-4	Screening	04/03/91	Abnormal	A-V BLOCK 1ST DEGREE
	250	Imipramine	Female	12/03/91	08/04/91	Screen Day 21	-5	Screening	07/03/91	Normal	
						Day 28	21	1-21 days	02/04/91	Abnormal	OTHER
							28	22-42 days	09/04/91	Normal	
	251	Imipramine	Female	20/03/91	12/04/91	Screen Day 21	-2	Screening	18/03/91	Normal	
							21	1-21 days	10/04/91	Normal	
	252	Reboxetine	Female	02/04/91	20/04/91	Screen Day 21	-5	Screening	28/03/91	Normal	
							18	1-21 days	20/04/91	Normal	
	253	Reboxetine	Female	02/04/91	08/04/91	Screen	-18	Screening	15/03/91	Normal	
	254	Imipramine	Female	09/04/91	16/04/91	Screen Day 14	-4	Screening	05/04/91	Normal	
							8	1-21 days	17/04/91	Abnormal	LEFT AXIAL DEVIATION
	255	Reboxetine	Female	13/05/91	06/06/91	Screen	-5	Screening	08/05/91	Normal	

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26

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
9	255	Reboxetine	Female	13/05/91	06/06/91	Day 21	28	1-21 days	10/06/91	Abnormal	SINUS TACHYCARDIA (> 100)
	256	Imipramine	Female	27/05/91	08/07/91	Screen Day 42	-5 35	Screening 22-42 days	22/05/91 01/07/91	Normal Normal	
	257	Placebo	Male	25/06/91	01/07/91	Screen	-4	Screening	21/06/91	Normal	
	258	Placebo	Male	01/07/91	10/07/91	Screen	-5	Screening	26/06/91	Normal	
11	319	Placebo	Male	02/08/91	12/09/91	Screen Day 21 Day 42	-8 20 41	Screening 1-21 days 22-42 days	25/07/91 22/08/91 12/09/91	Normal Normal Normal	
	320	Imipramine	Male	17/08/91	26/09/91	Screen Day 21 Day 42	-9 20 44	Screening 1-21 days 22-42 days	08/08/91 06/09/91 30/09/91	Normal Normal Normal	
20	321	Placebo	Male	06/09/91	17/10/91	Screen Day 21 Day 42	-14 20 41	Screening 1-21 days 22-42 days	23/08/91 26/09/91 17/10/91	Abnormal Abnormal Abnormal	LEFT AXIAL DEVIATION LEFT AXIAL DEVIATION LEFT AXIAL DEVIATION
08	322	Reboxetine	Female	27/09/91	07/11/91	Screen Day 21 Day 42	-8 20 41	Screening 1-21 days 22-42 days	19/09/91 17/10/91 07/11/91	Abnormal Abnormal Abnormal	SINUS BRADYCARDIA (< 60) PREVIOUS MYOCARDIAL INFARCTION PREVIOUS MYOCARDIAL INFARCTION PREVIOUS MYOCARDIAL INFARCTION
08	323	Reboxetine	Male	15/11/91	26/12/91	Screen Day 21 Day 42	-9 20 63	Screening 1-21 days 22-42 days	06/11/91 05/12/91 17/01/92	Abnormal Abnormal Abnormal	LEFT VENTRICULAR HYPERTROPHY LEFT VENTRICULAR HYPERTROPHY SINUS TACHYCARDIA (> 100) LEFT VENTRICULAR HYPERTROPHY
09	324	Imipramine	Male	06/12/91	16/01/92	Screen Day 21 Day 42	-4 21 41	Screening 1-21 days 22-42 days	02/12/91 27/12/91 16/01/92	Normal Normal Normal	
	325	Reboxetine	Male	13/12/91	23/01/92	Screen Day 21 Day 42	-4 20 41	Screening 1-21 days 22-42 days	09/12/91 02/01/92 23/01/92	Abnormal Abnormal Abnormal	NON SPECIFIC ST-T WAVE CHANGES NON SPECIFIC ST-T WAVE CHANGES NON SPECIFIC ST-T WAVE CHANGES

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27

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECC TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
11	326	Placebo	Male	16/01/92	27/02/92	Screen Day 21	-1 22	Screening 1-21 days	15/01/92 07/02/92	Normal Normal	
	327	Imipramine	Male	30/01/92	05/02/92	Screen	-6	Screening	24/01/92	Normal	
	328	Imipramine	Female	31/01/92	04/02/92	Screen	-2	Screening	29/01/92	Abnormal	SINUS BRADYCARDIA (< 60)
	329	Placebo	Female	10/04/92	21/05/92	Screen Day 21 Day 42	-9 20 40	Screening 1-21 days 22-42 days	01/04/92 30/04/92 20/05/92	Abnormal Normal Normal	MYOCARDIAL ISCHEMIA
	330	Reboxetine	Male	09/04/92	21/05/92	Screen Day 21	-2 21	Screening 1-21 days	07/04/92 30/04/92	Normal Normal	
	331	Imipramine	Male	17/04/92	28/05/92	Screen	-9	Screening	08/04/92	Abnormal	MYOCARDIAL ISCHEMIA LEFT BUNDLE BRANCH BLOCK LEFT ANTERIOR HEMIBLOCK LEFT BUNDLE BRANCH BLOCK LEFT ANTERIOR HEMIBLOCK MYOCARDIAL ISCHEMIA LEFT BUNDLE BRANCH BLOCK LEFT ANTERIOR HEMIBLOCK
	332	Reboxetine	Male	19/05/92	29/06/92	Screen Day 21 Day 42	-6 21 51	Screening 1-21 days 22-42 days	13/05/92 09/06/92 09/07/92	Abnormal Abnormal Abnormal	SINUS BRADYCARDIA (< 60) LEFT VENTRICULAR HYPERTROPHY LEFT VENTRICULAR HYPERTROPHY
	333	Placebo	Male	27/05/92	07/07/92	Screen Day 21 Day 42	-8 20 42	Screening 1-21 days 22-42 days	19/05/92 16/06/92 08/07/92	Normal Normal Normal	
	334	Reboxetine	Female	29/05/92	31/05/92	Screen	-8	Screening	21/05/92	Normal	
	335	Placebo	Male	03/06/92	14/07/92	Screen Day 21 Day 42	-15 27 41	Screening 1-21 days 22-42 days	19/05/92 30/06/92 14/07/92	Normal Normal Normal	
	336	Imipramine	Female	18/06/92	25/06/92	Screen	-2	Screening	16/06/92	Normal	

9550082

2090

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

28

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	F.C.G.		
				Start date	End date				Date	Value	Abnormality
11	337	Reboxetine	Female	02/07/92	13/08/92	Screen	-9	Screening	23/06/92	Normal	
						Day 21	21	1-21 days	23/07/92	Normal	
12	338	Imipramine	Male	23/07/92	30/07/92	Screen	-8	Screening	15/07/92	Normal	
						Day 42	43	22-42 days	14/08/92	Normal	
12	367	Reboxetine	Female	20/12/91	30/01/92	Screen	-3	Screening	17/12/91	Abnormal	NON SPECIFIC ST-T WAVE CHANGES
						Day 21	21	1-21 days	10/01/92	Normal	
12	368	Placebo	Female	24/12/91	03/02/92	Screen	-5	Screening	19/12/91	Normal	
						Day 21	21	1-21 days	10/01/92	Normal	
12	369	Imipramine	Female	23/04/92	13/05/92	Screen	-1	Screening	04/02/92	Abnormal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL
						Day 21	20	1-21 days	13/05/92	Normal	
12	370	Placebo	Male	29/04/92	20/05/92	Screen	-2	Screening	27/04/92	Abnormal	LEFT VENTRICULAR HYPERTROPHY CONDUCTION DISORDER
						Day 21	20	1-21 days	19/05/92	Abnormal	LEFT ANTERIOR HEMIBLOCK NON SPECIFIC ST-T WAVE CHANGES
12	371	Imipramine	Female	01/05/92	06/05/92	Screen	-10	Screening	21/04/92	Abnormal	MYOCARDIAL ISCHEMIA
						Day 7	7	1-21 days	08/05/92	Abnormal	MYOCARDIAL ISCHEMIA
12	372	Reboxetine	Male	02/06/92	13/07/92	Screen	-1	Screening	01/06/92	Normal	
						Day 21	20	1-21 days	22/06/92	Abnormal	SINUS BRADYCARDIA (< 60)
12	373	Reboxetine	Male	05/06/92	14/07/92	Screen	0	Screening	05/06/92	Normal	
						Day 21	20	1-21 days	23/06/92	Normal	
12	374	Placebo	Female	09/06/92	05/07/92	Screen	0	Screening	09/06/92	Normal	
						Day 21	21	1-21 days	30/06/92	Normal	
12	375	Imipramine	Male	17/06/92	18/06/92	Screen	-2	Screening	15/06/92	Normal	
						Day 28	27	22-42 days	06/07/92	Normal	

9550082

2091

PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/015
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
											F.C.G.
13	13	Placebo	Male	13/04/91	24/05/91	Screen Day 21 Day 42	-2 20 41	Screening 1-21 days 22-42 days	11/04/91 03/05/91 24/05/91	Normal Normal Normal	
14	14	Placebo	Male	02/07/91	13/08/91	Screen Day 21 Day 42	7 22 44	Screening 1-21 days 22-42 days	09/07/91 24/07/91 15/08/91	Normal Normal Normal	
15	15	Imipramine	Female	05/07/91	15/08/91	Screen Day 21 Day 42	-1 20 40	Screening 1-21 days 22-42 days	04/07/91 25/07/91 14/08/91	Normal Normal Normal	
16	16	Imipramine	Male	03/12/91	16/01/92	Screen Day 28 Day 42	0 34 48	Screening 22-42 days 22-42 days	03/12/91 06/01/92 20/01/92	Normal Normal Normal	
17	17	Reboxetine	Male	21/05/92	01/07/92	Screen Day 21 Day 42	2 21 42	Screening 1-21 days 22-42 days	23/05/92 11/06/92 02/07/92	Normal Normal Normal	
18	18	Reboxetine	Male	24/06/92	02/08/92	Screen Day 21 Day 42	2 19 40	Screening 1-21 days 22-42 days	26/06/92 13/07/92 03/08/92	Normal Normal Normal	
409	409	Reboxetine	Male	10/12/91	20/01/92	Screen Day 21 Day 42	0 24 63	Screening 1-21 days 22-42 days	10/12/91 03/01/92 22/01/92	Normal Normal Normal	
410	410	Placebo	Male	14/02/92	26/03/92	Screen Day 21 Day 42	-3 20 42	Screening 1-21 days 22-42 days	11/02/92 05/03/92 27/03/92	Normal Abnormal Normal	SINUS TACHYCARDIA (> 100)
411	411	Imipramine	Female	28/03/92	08/05/92	Screen Day 21 Day 42	-2 24 38	Screening 1-21 days 22-42 days	26/03/92 21/04/92 05/05/92	Normal Normal Normal	
423	423	Placebo	Male	14/09/92	27/10/92	Screen Day 21 Day 42	1 21 45	Screening 1-21 days 22-42 days	15/09/92 05/10/92 29/10/92	Normal Normal Normal	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
14	19	Reboxetine	Female	10/04/92	06/05/92	Screen	-7	Screening	03/04/92	Abnormal	NON SPECIFIC ST-T WAVE CHANGES
						Day 28	27	22-42 days	07/05/92	Abnormal	NON SPECIFIC ST-T WAVE CHANGES
						Screen	-2	Screening	27/04/92	Abnormal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
20	Imipramine	Female	29/04/92	09/06/92	Day 21	21	1-21 days	20/05/92	Abnormal	NON SPECIFIC ST-T WAVE CHANGES	
					Day 42	71	22-42 days	09/07/92	Abnormal	RIGHT BUNDLE BRANCH BLOCK	
					Screen	-4	Screening	27/04/92	Abnormal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	
21	Imipramine	Female	20/07/92	24/08/92	Screen	21	1-21 days	16/07/92	Normal		
					Day 21	21	1-21 days	10/08/92	Abnormal	PREVIOUS MYOCARDIAL INFARCTION	
					Day 35	35	22-42 days	24/08/92	Normal		
15	25	Reboxetine	Female	18/06/91	29/07/91	Screen	-1	Screening	17/06/91	Normal	
						Day 21	21	1-21 days	09/07/91	Normal	
						Day 42	42	22-42 days	30/07/91	Normal	
26	26	Placebo	Male	20/06/91	01/08/91	Screen	-3	Screening	17/06/91	Normal	
						Day 21	20	1-21 days	10/07/91	Normal	
						Day 42	42	22-42 days	01/08/91	Normal	
27	27	Imipramine	Female	02/07/91	13/08/91	Screen	-5	Screening	27/06/91	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 21	21	1-21 days	23/07/91	Normal	
						Day 42	42	22-42 days	13/08/91	Abnormal	SINUS BRADYCARDIA (< 60)
28	28	Reboxetine	Female	08/08/91	19/09/91	Screen	-2	Screening	06/08/91	Normal	
						Day 21	21	1-21 days	29/08/91	Normal	
						Day 42	43	22-42 days	20/09/91	Normal	
29	29	Placebo	Male	29/08/91	19/09/91	Screen	0	Screening	29/08/91	Normal	
						Day 21	21	1-21 days	19/09/91	Normal	
						Screen	0	Screening	03/09/91	Normal	
30	30	Imipramine	Female	05/09/91	15/10/91	Day 21	21	1-21 days	24/09/91	Normal	
						Day 42	42	22-42 days	15/10/91	Normal	
						Screen	0	Screening	04/10/91	Normal	
403	403	Imipramine	Female	04/10/91	14/11/91	Day 21	24	1-21 days	28/10/91	Normal	
						Day 42	41	22-42 days	14/11/91	Normal	
						Screen	0	Screening	04/10/91	Normal	

090177e1803f15a2\Approved\Approved On: 11-Nov-2002 22:51

31

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/015
Listing No.: 21.0

ECC TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
15	404	Reboxetine	Female	08/10/91	05/11/91	Screen Day 21	-28	Screening 21 1-21 days	10/09/91	Normal	Normal
	405	Placebo	Female	11/11/91	23/12/91	Screen Day 21 Day 42	0	Screening 21 1-21 days 42 22-42 days	11/11/91	Abnormal	SINUS BRADYCARDIA (< 60)
	406	Imipramine	Male	27/11/91	07/01/92	Screen Day 21 Day 42	0	Screening 20 1-21 days 41 22-42 days	02/12/91	Abnormal	SINUS BRADYCARDIA (< 60)
	407	Reboxetine	Female	03/12/91	14/01/92	Screen Day 21 Day 42	-1	Screening 21 1-21 days 42 22-42 days	17/12/91	Abnormal	SINUS TACHYCARDIA (> 100)
	408	Placebo	Female	20/01/92	04/03/92	Screen Day 21 Day 42	-5	Screening 22 1-21 days 44 22-42 days	02/12/91	Normal	Normal
	418	Placebo	Female	30/01/92	12/03/92	Screen Day 21 Day 42	0	Screening 21 1-21 days 42 22-42 days	24/12/91	Normal	Normal
	419	Placebo	Female	28/04/92	09/06/92	Screen Day 0 Day 21 Day 42	-1	Screening 0 Screening 21 1-21 days 42 22-42 days	15/01/92	Normal	Normal
									11/02/92	Normal	Normal
									04/03/92	Normal	Normal
									30/01/92	Normal	Normal
									20/02/92	Normal	Normal
									12/03/92	Normal	Normal
									27/04/92	Abnormal	SINUS BRADYCARDIA (< 60)
									28/04/92	Normal	Normal
									19/05/92	Normal	Normal
									09/06/92	Normal	Normal

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12.2.3 CRFs

Individual patient CRFs are filed in the Study Master File.

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